

MESTRADO INTEGRADO EM MEDICINA

Point prevalence of motor neuropathy in children and adolescents with type I diabetes mellitus

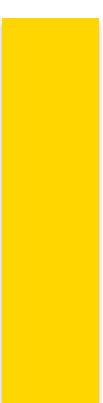
Joana Helena de Bourbon Faria Ribeiro
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Eu, _____Joana Helena de Bourbon Faria Ribeiro Lopes_____, abaixo assinado, nº mecanográfico _____201908122_____, estudante do 6º ano do Ciclo de Estudos Integrado em Medicina, na Faculdade de Medicina da Universidade do Porto, declaro ter actuado com absoluta integridade na elaboração do meu trabalho de Dissertação ou Monografia.

Neste sentido, confirmo que **NÃO** incorri em plágio (acto pelo qual um indivíduo, mesmo por omissão, assume a autoria de um determinado trabalho intelectual, ou partes dele). Mais declaro que todas as frases que retirei de trabalhos anteriores pertencentes a outros autores, foram referenciadas, ou redigidas com novas palavras, tendo colocado, neste caso, a citação da fonte bibliográfica.

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Ciências Médicas e da Saúde; Medicina Clínica

TÍTULO DISSERTAÇÃO/~~MONOGRAFIA~~ (riscar o que não interessa)

Point prevalence of motor neuropathy in children and adolescents with type 1 diabetes mellitus

ORIENTADOR

Dra. Cíntia Castro Correia

COORDINADOR (se aplicável)

Dra. Jacinta Fonseca

ASSINALE APENAS UMA DAS OPÇÕES:

É AUTORIZADA A REPRODUÇÃO INTEGRAL DESTA TRABALHO APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☒
É AUTORIZADA A REPRODUÇÃO PARCIAL DESTA TRABALHO (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☐
DE ACORDO COM A LEGISLAÇÃO EM VIGOR, (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) NÃO É PERMITIDA A REPRODUÇÃO DE QUALQUER PARTE DESTA TRABALHO.	☐

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☒ Não procedi à utilização de ferramentas de *chatbox* generativo baseadas em *large language models* para nenhuma das tarefas no contexto do meu trabalho de Dissertação ou Monografia

☐ Procedi à utilização de ferramentas de *chatbox* generativo baseadas em *large language models* no contexto do meu trabalho de Dissertação ou Monografia, encontrando-se todas as interações (*prompts* e respostas) transcritas em anexo bem como a indicação das aplicações utilizadas.

Neste sentido, confirmo que a eventual utilização de ferramentas de *chatbox* generativo baseadas em *large language models* no contexto do meu trabalho de Dissertação ou Monografia foi exclusivamente descrita na sequência de *prompts* e respostas transcritos em anexo e nas aplicações indicadas.

Faculdade de Medicina da Universidade do Porto, _18_/__03_/__2025____

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Dedicatória

Em primeiro lugar, gostaria de expressar a minha profunda gratidão à minha família, em especial aos meus pais, pelo apoio incondicional ao longo de todos os anos deste curso e, em particular, neste último ano, uma fase tão importante e desafiante da minha vida. Agradeço, de coração, todos os sacrifícios que fizeram para me proporcionarem o maior conforto e felicidade possíveis, bem como as ferramentas que tornaram mais fácil a concretização dos meus objetivos. Acima de tudo, sou imensamente grata por estarem sempre ao meu lado, com um abraço afetuoso e um orgulho inabalável em mim. Agradeço também ao meu irmão que, tendo concluído a sua tese de mestrado no ano passado, me foi dando dicas valiosas ao longo deste percurso. Um obrigado especial ao Diogo, por ser o meu porto de abrigo, por me dar confiança e motivação quando mais precisei.

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Point prevalence of motor neuropathy in children and adolescents with type I diabetes mellitus

Short title: Motor neuropathy screening

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Abstract

Objectives: To conduct a screening for motor neuropathy in children and adolescents with type I diabetes to assess its point prevalence and to analyse potential risk factors associated with any positive motor neuropathy diagnosis.

Methods: This is a cross-sectional study involving children aged 12 to 18 years who have been diagnosed with diabetes for five or more years and are receiving treatment with an insulin pump. All participants underwent a neurological examination and were questioned about symptoms of neuropathy. A nerve conduction study was conducted to evaluate the median, ulnar, common peroneal, and tibial motor nerves. Sensory nerves were also examined. The F-wave response of the tibial nerve was analysed, and needle electromyography was performed on a proximal and distal muscle of the lower limb.

Results: A total of 29 children completed the study (mean age: 15.34 ± 1.56 years; mean duration of diabetes: 11.93 ± 2.84 years; HbA1c levels: 7.50 ± 1.17 %). Results were normal, indicating adequate motor nerve integration and excluding the presence of motor neuropathy as well as peripheral neuropathy, even at subclinical level.

Conclusion: In our studied population, which receives tight monitoring and support for diabetes management, using nerve conduction studies to detect early subclinical motor neuropathy shows no clear benefit. This finding was consistent even among individuals with poor metabolic control, altered albumin/creatinine ratio, and diabetes duration over 10 years, with no abnormalities observed. We recommend following the latest guidelines provided by the American Diabetes Association (ADA).

Keywords: Motor neuropathy; nerve conduction studies; type I diabetes mellitus; paediatric;

Resumo

Objetivos: Realizar um rastreio de neuropatia motora em crianças e adolescentes com diabetes tipo I, determinando a sua prevalência pontual e analisando potenciais fatores de risco associados a um diagnóstico positivo.

Métodos: Trata-se de um estudo transversal envolvendo crianças dos 12 aos 18 anos, com diabetes tipo I há pelo menos cinco anos e em tratamento com bomba de insulina. Todos os participantes foram submetidos a um exame neurológico e questionados sobre sintomas de neuropatia. Foi também realizado um estudo da condução nervosa dos nervos motores mediano, cubital, peroneal comum e tibial. Procedeu-se igualmente à avaliação dos nervos sensoriais. Analisou-se a resposta da onda F do nervo tibial e realizou-se eletromiografia de agulha num músculo proximal e distal de um membro inferior.

Resultados: O estudo incluiu 29 crianças (idade média: $15,34 \pm 1,56$ anos; duração média da diabetes: $11,93 \pm 2,84$ anos; HbA1c: $7,50 \pm 1,17$ %). Os resultados foram normais, indicando integridade da função motora e ausência de neuropatia motora bem como neuropatia periférica, mesmo em fase subclínica.

Conclusões: Na nossa população estudada, que recebe um bom acompanhamento e um apoio rigoroso na gestão da diabetes, a utilização de testes de condução nervosa para detetar precocemente a neuropatia motora subclínica não apresenta um benefício claro. Este achado foi consistente mesmo entre os indivíduos com mau controlo metabólico, relação albumina/creatinina alterada e duração da diabetes superior a 10 anos, onde não foram observadas quaisquer anomalias. Recomendamos que sejam seguidas as últimas diretrizes da American Diabetes Association (ADA).

Introduction

Background

Type 1 diabetes(T1DM)

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disorder characterized by insulinitis, an inflammatory lesion caused by autoreactive T-cells that infiltrate the islets, leading to the destruction of β -cells and ultimately resulting in insulin deficiency(1–3). The most common symptoms resulting from hyperglycaemia include polyuria, weight loss, polydipsia, and, in some cases, diabetic ketoacidosis. Diagnosis is based on clinical symptoms and glucose monitoring(4–6).

T1DM progresses through three stages. Stage 1, known as preclinical type 1 diabetes, is marked by the presence of two or more autoantibodies despite normal blood glucose levels. Stages 2 and 3 indicate a progression from dysglycemia to overt symptomatic hyperglycaemia(5).

It is the most common chronic endocrine disease among the paediatric population(7).

Diabetic peripheral neuropathy

Prolonged T1DM can cause early microvascular complications like retinopathy, nephropathy, and neuropathy, while macrovascular consequences like arteriosclerosis tend to occur later(8). Diabetic neuropathies affect the nervous system, causing various symptoms due to abnormalities in sensory, motor, and autonomic nerve fibres, which are classified based on clinical features(9).

Chronic sensorimotor distal symmetric polyneuropathy (DSPN) and autonomic neuropathy are the two most common types of neuropathies(9–11). Diabetic peripheral neuropathy (DPN) falls under the DSPN category. DPN is defined as symptoms or signs of peripheral nerve dysfunction in individuals with diabetes, excluding other causes(11). It is a common complication that can lead to significant disability, reduced quality of life, and a substantial economic burden(12).

It is estimated that up to 50% of individuals with long-term diabetes may be affected by this complication(11,13). This percentage could rise to 100% when more precise diagnostic methods, such as nerve conduction studies, are used(11). The prevalence of these complications is likely underestimated, as they often remain subclinical in younger age groups(9,11).

Although younger age at onset, longer duration of diabetes, and a history of diabetic complications are recognised risk factors, the primary driver is chronic hyperglycemia(9,11). This sustained metabolic imbalance leads to the formation of advanced glycation end products and activation of polyol, glycolysis and hexamine biological pathways which trigger oxidative stress at the cellular level, resulting in vascular and neuronal damage. Therefore, it is crucial to maintain good metabolic control(11).

DPN affects both myelinated and unmyelinated nerve fibres. Pain mainly results from damage to thin, unmyelinated fibres, while impairment of large, myelinated fibres can lead to gait instability, increasing fall risk(2).

Common symptoms like numbness, tingling, allodynia, and a shock-like sensation, indicate somatic involvement(11).

According to the American Diabetes Association (ADA), screening for DPN is recommended five years after diagnosis in type 1 diabetic patients. The frequency of this screening should be annual or semestral and must include clinical history and a physical examination(13).

Motor neuropathy and nerve conduction studies

Motor involvement in DPN is often overlooked compared to sensory dysfunction(14). However, motor impairment increases fall risk, affects gait and balance, and can lead to foot deformities like hammer toes, contributing to chronic irritation and ulceration(14,15).

Multiple studies using nerve conduction tests (NCS) have shown the ability to detect subclinical motor involvement, revealing reduced motor nerve conduction velocity (MNCV) and amplitude, indicative of nerve deterioration. Early MNCV reduction is linked to nodal dysfunction, axonal swelling, oxidative stress, and metabolic disturbances. Over time, axonal atrophy and segmental demyelination leads to conduction blocks. When detected early, these conditions can be reversed with proper metabolic control, including insulin administration; however, after a few months, these abnormalities become irreversible(14).

Studies emphasize the importance of NCSs in detecting early motor dysfunction, revealing a high prevalence of subclinical neuropathy in diabetic patients and indicating that motor involvement is more frequent than previously recognised(10,14,16). Longitudinal research demonstrates a significant increase in DPN over time, with

subclinical cases nearly doubling after several years, underscoring the progressive nature of the condition(12).

These findings substantiate the hypothesis that NCSs provide significant advantages for early screening and detection of motor neuropathy. By identifying nerve dysfunction before clinical symptoms emerge, these tests enable earlier interventions, potentially slowing progression and preventing severe motor complications. Although subclinical nerve function abnormalities may not directly predict the onset of clinical neuropathy, certain changes in nerve function indicate damage that, when combined with other local injuries, may become clinically significant(17).

Despite extensive research on peripheral neuropathy in type I diabetes, the pattern of nerve involvement remains controversial. The frequent involvement of the common peroneal nerve in some studies further suggests a targeted approach in screening protocols, making NCS a valuable tool beyond standard neurological exams(8,10).

This method can be time-consuming, expensive, and uncomfortable for many paediatric patients. However, it is less dependent on patient cooperation, making it less subjective. In children and adolescents with T1DM, early signs of neuropathy are often minimal or absent, making clinical exams less reliable in this group(9,18). Nerve conduction studies can therefore be a more effective diagnostic tool, as they can detect the condition at a subclinical stage.

Objectives

The main objective is to evaluate the point prevalence of motor neuropathy in children and adolescents with a 5-year or more diagnosis of type I diabetes using nerve conduction studies. We will analyse various biochemical and clinical parameters of each individual to evaluate their metabolic control. Subsequently, to potentially identify factors that may increase the risk of developing motor neuropathy, we intend to evaluate positive motor neuropathy diagnoses with these parameters.

Methods

This cross-sectional analytical study was conducted at the paediatric endocrinology department of the Centro Hospitalar Universitário S. João (CHUSJ), from September 2024 to March 2025.

We reviewed all the children who attended the semester evaluation consultation for their T1DM diagnosis between September 2024 and January 2025. Among them, we found a total of 42 children who met our inclusion criteria: they were aged between 10 and 18 years, had been diagnosed with T1DM for over five years, and were being treated with an insulin pump. We then excluded any children who had been diagnosed with neuropathy due to causes other than T1DM, such as infections, connective tissue diseases, medications, or nutritional deficiencies. We also excluded children with a family history of hereditary neuropathy, those with types of diabetes other than type 1, and children using medications that could potentially affect peripheral nerve function.

The total number of participants was determined based on a review of similar studies, the total number of children monitored at CHUSJ, and practical considerations such as time constraints and the availability required to conduct both NCS and neurological examinations.

The study was approved by the Ethics committee of CHUSJ. Written informed consent was obtained from patients and their parents. Participants had the right to withdraw from the study at any time. Confidentiality and the well-being of patients were prioritized throughout the study.

The enrolled children underwent a standardized and systematic summary neurological examination which included ankle, patellar, bicipital and tricipital reflex, assessment of muscular force, vibration and cutaneous sensation. All evaluations were conducted by a single individual to eliminate interobserver bias, thereby reducing variability in the application and interpretation of the neurological examination.

Vibration was evaluated using a 128 Hz tuning fork placed on the dorsum of the great toe, just proximal to the nail bed and scored as (=1) if present (=0) if absent.

The analysis of cutaneous touch sensation was conducted using the 10g Semmes-Weinstein monofilament on the plantar surface of the great toe and the bases of the first and fifth metatarsals on both feet. The monofilament was applied perpendicularly to intact skin with enough pressure to cause it to bend, maintaining contact for no longer than two seconds. The individuals were with their eyes closed and described whether

they felt the pressure and where they felt it. The test was assessed in three specific sites, making three applications at each site while alternating between actual touches and simulated ones. Cutaneous sensation was considered present if at least two out of three responses were correct for each site, with a score of (=1) if present and (=0) if absent(19).

The assessment of muscular force involved extending and flexing the ankle, knee, and elbow, which was then graded using the Medical Research Council (MRC) scale from zero to five. Muscle power was classified as follows: normal for grades 4–5, reduced for grade 3, and severely reduced for grades 0–2.

The reflexes were evaluated using a reflex hammer and scored as normal (=0), present with reinforcement (=1) and decreased or absent (=2).

Following the neurological summary examination, participants were inquired about the presence of various symptoms suggestive of neuropathy, including cramps, numbness, tingling, burning sensations, electric shock-like sensations, instability while walking, fatigue, hyperalgesia, and allodynia. The symptoms were classified as follows: (=1) if present and (=0) if absent.

The electrophysiological test was done by the dantec keypoint electromyography machine by a single neurophysiologist who was blinded to the patient's clinical and medical history. The exam was, in general, well tolerated by the children and adolescents. The temperature was checked each time before placing the electrodes, ensuring it was above 30°C. When necessary, arms and legs were warmed with hot water. The ground electrode was placed midway between the stimulation and the recording electrodes.

Motor conduction studies were performed bilaterally on the median, ulnar, common peroneal, and tibial motor nerves. Conduction velocity (CV) on the tibial nerve was not measured, as it can be uncomfortable. Instead, we opted to measure the F wave response, which was recorded in both the right and left tibial nerves. This technique has a higher sensitivity as it studies also proximal conduction(20). F minimal latency (m s) was considered normal if equal to or lower than 55 m s.

Table 2 shows the reference cut-off values considered normal and routinely used in clinical practice. The electrophysiological findings were analysed by a neurologist trained in clinical neurophysiology and neuromuscular disorders, taking into account the individual context and the reference values. They were determined through a literature review by neurophysiology specialists, based on the American Association of

Neuromuscular & Electrodiagnostic Medicine (AANEM) guidelines and adapted to the Portuguese population(21).

Needle electromyography (EMG) was conducted on all individuals for the right peroneus tertius and right vastus medialis, as this test shows greater sensitivity for axonal motor damage. The reduction in the amplitude of the compound muscle action potential (CMAP), with either normal or slightly decreased CV, or a modest increase in distal motor latency (DML) can support axonal damage(22).

Primary demyelination can be considered when there is a marked reduction in motor CV or grossly increased DMLs or minimum F-wave latencies(22).

Data were collected and analysed, including age, gender, height, weight, body mass index (BMI), duration of diabetes, haemoglobin A1c (HbA1c), fasting plasma glucose, lipid profile (HDL, LDL, total cholesterol, triglycerides), time in range (TIR) percentage, coefficient of variation, vitamin D levels, urea, creatinine, albuminuria and the spot albumin-to-creatinine ratio. Metabolic control was considered good if HbA1c levels were between 6.5 % and 7.5 %, moderate if between 7.6 % and 9.0 % and poor if above 9.0 %(8).

Statistical Analysis

Data are presented as arithmetic means $\pm$ standard deviations (SD). Three missing conduction velocity values were imputed using the mean after confirming a normal distribution (highlighted in orange in supplementary material, Table 4). This preserved the sample size. Two individuals had clinical analyses performed privately, with only confirmation of normal results available. One individual lacked TIR (%) and variation coefficient (%) due to the absence of FreeStyle Libre monitoring (also noted in blue, Table 4).

Results

Out of the 42 individuals assessed for eligibility, 2 were initially excluded from the study: one had Charcot-Marie-Tooth syndrome and the other had a cognitive disorder. Additionally, 3 individuals declined to participate. Ultimately, a total of 29 participants completed the study (Figure 1).

Of the 37 individuals who initially agreed to participate, a total of 8 did not attend the scheduled electromyography session. Some individuals gave no reason for their absence, while others were hesitant to miss classes solely for the purpose of the exam. Due to time constraints and scheduling logistics with the neurophysiology doctor, it was difficult to arrange the exam on the days when they had other appointments. If it had been possible, we would have achieved better adhesion.

The mean age of the patients was 15.34 ± 1.56 years, 34.48 % were female and 65.52 % were male. The mean age duration of T1DM was 11.93 ± 2.84 years. The biochemical characteristics of the patients are shown in Table 3. The HbA1c was 7.50 ± 1.17 %, with 37 % having values of HbA1c above 7.5 %. In addition, 68 % had a time in range (%) less than 70 % and 61 % had a coefficient of variation (%) greater than 36 %. None of our patients had retinopathy, and only one individual showed an altered albumin/creatinine ratio.

During the summary neurological examination, no abnormalities were found, except in four individuals who exhibited decreased patellar and achilles reflexes. Among these, one reported numbness in the legs. No other complaints were noted.

Ultimately, all NCS results were normal. Table 1 summarises the mean values ($\pm$ SD) for latency, velocity, and amplitude of the peroneal, posterior tibial, median, and ulnar motor nerves.

Table 1-Nerve conduction study results (latency, amplitude, and velocity) presented as mean $\pm$ standard deviation.

Nerve	Latency (m s)	Amplitude (M v)	Velocity (m s ⁻¹)
Left Peroneal	4.11 ± 0.53	5.62 ± 2.17	49.61 ± 3.47
Right Peroneal	3.79 ± 0.35	6.33 ± 2.10	48.69 ± 3.26
Left Tibial	4.11 ± 0.54	11.39 ± 3.65	-
Right Tibial	4.24 ± 0.56	11.47 ± 3.00	-
Left Medianus	3.39 ± 0.33	8.46 ± 1.97	56.90 ± 3.50
Right Medianus	3.39 ± 0.34	9.35 ± 1.93	58.02 ± 2.66
Left Ulnaris	2.56 ± 0.29	8.68 ± 1.29	60.99 ± 4.43
Right Ulnaris	2.66 ± 0.30	8.62 ± 1.55	60.12 ± 4.90

The EMG results were normal, indicating no axonal damage. Additionally, F minimum latency values were within the normal range (below 55 m s) at 45.59 ± 3.73 m s in the right tibialis and 45.77 ± 3.96 m s in the left tibialis.

Discussion

Our study found no evidence of subclinical motor neuropathy in any of the participants, suggesting that motor nerve function remained preserved in this population. This contrasts with previous studies that reported a higher prevalence of motor involvement.

Abuelwafaa et al. 2019 studied 50 diabetic patients aged 10 - 18 years and found that 88% had electrophysiological evidence of peripheral neuropathy, primarily affecting motor function (68.2%) with no cases of pure sensory neuropathy(10). The most common finding was conduction slowing, particularly in the common peroneal nerve. This finding is noted in other studies, highlighting the significance of motor involvement(16,23). They used a stricter conduction velocity threshold of 46.7 m s^{-1} compared to our 40 m s^{-1} , which may explain their higher prevalence rates(10). This study was conducted in Sudan, where limited healthcare resources and poor diabetes management may have contributed to the increased prevalence of neuropathy. The mean HbA1c level in their population was 11.28 ± 2.75 %, compared to our study's mean of 7.50 ± 1.17 %. This indicates poorer metabolic control, despite a shorter disease duration of 10.21 ± 3.93 years(10).

Singh et al. 2022 study, out of also 50 children aged 8-18 years, 56 % exhibiting subclinical neuropathy on NCS, with 40 % having pure motor, 2 % pure sensory, and 14 % mixed motor-sensory neuropathy(8). The participants had poorer metabolic control with HbA1c of 9.14 ± 2.10 % and the higher prevalence may also be due to ethnic and genetic differences, limited healthcare infrastructure and environmental factors in India. Glycaemic variability, including the frequency of hypoglycaemia and hyperglycaemia, and different diagnostic criteria may also contribute. The peroneal nerve was also the most affected, with significant risk factors including poor glycaemic control (HbA1c > 9 %) and diabetes duration of over five years. However, this pattern is not

consistently observed in other studies, leading to the belief that the development of neuropathy in childhood is neurophysiologically heterogeneous(7,12,17).

On the other hand, Walter-Holiner et al. 2018 conducted a cohort study with a 5-year follow-up, in Austria with a total of 38 patients aged 9-18 years(12). At baseline, the prevalence of diabetic peripheral neuropathy (DPN) diagnosed through neurological examination was 13.2 %, while nerve conduction velocity (NCV) testing detected DPN in 31.6 %, indicating a high prevalence of subclinical cases. After five years, clinically diagnosed DPN increased to 34.2 % ($p=0.039$), while subclinical DPN rose to 63.2 % ($p=0.002$), with the most significant electrophysiological changes observed in the tibial sensory nerve(12). Some research indicates that the motor nervous system is more resistant than the sensory nervous system. This difference may be due to anatomy: dorsal root ganglion neurons are outside the blood-brain barrier, while motor neurons are protected within the ventral horn of the spinal cord(7,24,25). While not the main focus of this study, NCSs were also performed on the median, ulnar, and sural sensory nerves. These revealed no abnormalities, thus providing no evidence of diabetic peripheral neuropathy. In addition, they used reference values like ours for conduction velocity in motor nerves. And so given Austria's advanced healthcare system, the high prevalence cannot be due to limited resources or poor metabolic monitoring, as shown in other studies. Their mean HbA1c was 8.1 ± 1.2 %, comparable to ours, but with a shorter disease duration of 5.6 ± 3.2 years.

There were one or two individual measurements that were close to the reference range, particularly the common peroneal nerve velocity and F minimum latency. Notably, this phenomenon has been observed in taller individuals with no clinical symptoms and no changes in the physical and neurological exam. Studies indicate that taller people typically exhibit lower nerve conduction velocities and higher F wave latencies, which may represent a physiological variation rather than a pathological one(16,26). Secondly, there may also be minor technical factors such as electrode positioning which can introduce small discrepancies in motor nerve assessments. These considerations highlight the need for cautious interpretation of borderline values to avoid overestimating pathological findings.

In instances of isolated borderline values, it is crucial to consider the broader context, potential concomitant alterations like altered tibial F waves, altered needle electromyography, clinical symptoms, changes in physical neurological exam and the

individual's height. For these individuals, a follow-up evaluation is recommended within a five-year period to determine whether there have been any significant changes in the values compared to the initial assessment. If any changes are observed, it may be appropriate to consider the onset of subclinical motor neuropathy.

Consistent and reliable results were achieved through standardized neurological and electrophysiological assessments, which offered a comprehensive and objective evaluation of neuropathy in patients with T1DM. This also ensured comparability across different settings and populations. It is a relatively underexplored area, especially in our Portuguese population contributing to new knowledge to the field.

In addition, by having a single examiner conduct the neurological exam, inter-observer variability was minimized, enhancing the study's internal validity. However, misinterpretation or subtle variations in reflex evaluations could account for the alterations observed in the four cases. Furthermore, all NCS and EMG assessments were performed by the same highly experienced neurophysiologist, blinded to the patient's clinical and medical history. This approach minimized, once again, interobserver variability while also reducing observer bias.

Some factors may limit the study's generalisability. It was conducted in a single centre, CHUSJ, a hospital with experienced physicians and systematic treatment monitoring. This may not fully represent the broader paediatric T1DM population in other hospitals.

This study may be subject to some healthy user bias, as some children or adolescents who chose not to participate had poorer metabolic control and appeared to be less concerned about their health.

There are scarce reference values of electrophysiological results in a healthy paediatric population and so incorporating a healthy control group in a cohort study for comparison would improve external validity. However, it would be difficult to get approval from the ethics committee. Although we did not use a control group for reference and comparison, relying instead on fixed reference values, we could possibly say that our individual and mean $\pm$ SD values were very similar to those of control groups used as reference in many studies. There could be some doubt regarding the conduction velocity of the common peroneal nerve, which could eventually show statistical significance if analysed with values from control groups in other studies. Nonetheless, we wouldn't consider these individual values to be pathological, given the clinical context, the height of the patients, and additional findings such as normal tibial F

waves and needle electromyography, which are more sensitive indicators(17,23,27). Still, we did not take this approach because no similar study has been conducted in a Portuguese population with comparable characteristics. Using control groups from studies conducted in other countries could introduce bias due to population differences like genetic background, environmental factors, healthcare systems, and lifestyle that could influence the results.

Conclusion

This study indicates that, within our population, where patients receive thorough monitoring and support for their diabetes management, there is no discernible benefit of employing nerve conduction studies, like electromyography, for the purpose of diagnosing or detecting subclinical motor neuropathy. Even children and adolescents with poor metabolic control, altered albumin/creatinine ratios, and a long duration of diabetes exceeding 10 years showed no abnormalities in our study. There is still no consensus on the pattern of nerve involvement and histological abnormalities (demyelination or axonal degeneration), so further research is needed in this area to provide more conclusive information on the possibility of primary and secondary prevention and to improve quality of life. The varying prevalence rates presented are mostly due to the different criteria and lack of standardized characterization of DPN(23).

For, now we recommend using the electrophysiological diagnostic method only in accordance with the guidelines established by the American Diabetes Association (ADA). This recommendation applies specifically when clinical features are atypical or when a diagnosis remains uncertain after a comprehensive medical history and basic clinical assessments have been conducted(13).

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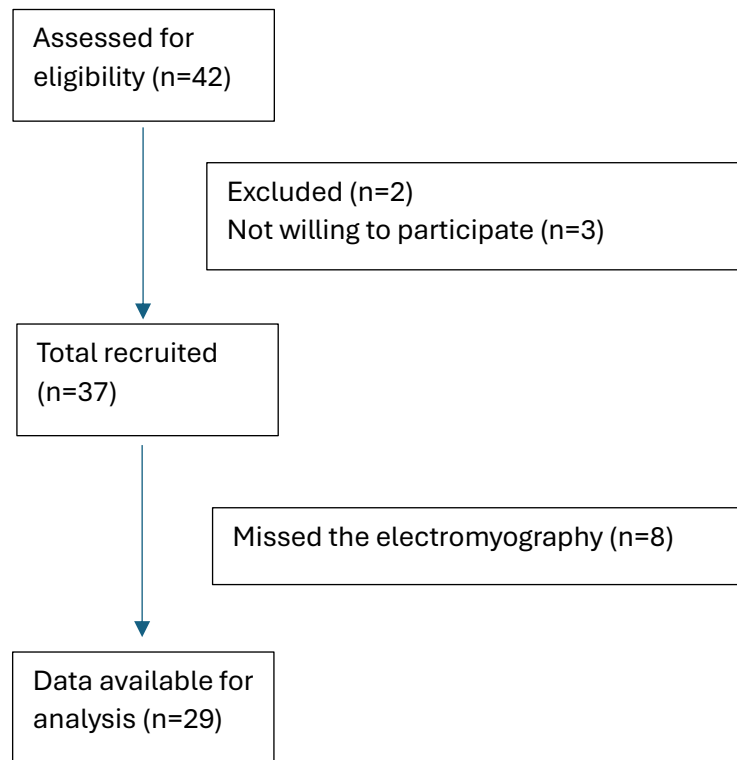


Figure 1-Flow diagram for participant recruitment

Table 2-Reference values for nerve conduction studies that are considered normal.

Nerve	Estimuli	Response registration	Distal Latency (m s)	Amplitude (M v)	Velocity (m s ⁻¹)	Distance (cm)
Peroneal	Ankle	Extensor digitorum brevis	≤ 6.0	≥ 2.0*	-	
		Extensor digitorum brevis	-	-	≥ 40	
Tibial	Posterior to the medial malleolus	Hallux abducor	≤ 6.0	≥ 4.0*	-	
Medianus	wrist	Abductor pollicis brevis	≤ 4.2	≥ 4.0	≥ 50	8.0
Ulnaris	Wrist	Abductor digiti minimi	≤ 3,6	≥ 6,0		8 -12
	Below elbow	Abductor digiti minimi			≥ 50	

*Compare with the contralateral

Table 3-Profile of biochemical parameters in study participants

Parameters	Cases (%) n=29
1. BMI (Percentile)	
< P3 (Underweight)	0 (0 %)
P3 - P85 (Normal)	21 (72 %)
P85 - P97 (Excess weight)	7 (24 %)
> P97 (obesity)	1 (3 %)
2. Fasting plasma glucose (mg dL ⁻¹) (178 ± 40.86)	
< 100 mg dL ⁻¹	1 (4 %)
100 - 125 mg dL ⁻¹	1 (4 %)
126 - 200 mg dL ⁻¹	19 (70 %)
> 200 mg dL ⁻¹	8 (30 %)
3. HbA1c (%) (7.50 ± 1.17)	
< 6.5 %	3 (11 %)
6.5 % - 7.5 %	16 (59 %)
7.6 % - 9.0 %	7 (26 %)
> 9.0 %	3 (11 %)
	Cases (%) n=28
4. Spot urinary albumin/creatinine ratio (mg g ⁻¹) (7.15 ± 9.02)	
< 30 mg g ⁻¹ (Normal)	27 (96 %)
30 - 300 mg g ⁻¹ (microalbuminuria present)	1 (4 %)
Spot urinary Albuminuria (mg L ⁻¹) (12.60± 23.61)	
< 20 mg L ⁻¹ (Normal)	25 (89 %)
> 20mg L ⁻¹ (Albuminuria)	3 (11 %)
5. Urea (mg dL ⁻¹) (28.57 ± 6.43)	
10.00 - 50 mg dL ⁻¹ (Normal)	28 (100 %)
> 50 mg dL ⁻¹	0 (0 %)
6. Creatinine (mg dL ⁻¹) (0.66 ± 0.14)	
0.67 mg dL ⁻¹ - 1.17 mg dL ⁻¹ (Normal)	15 (54 %)
< 0,67 mg dL ⁻¹ & > 1.17 mg dL ⁻¹ (Abnormal)	13 (46 %)
1. Time in range(%) (57 ± 0.19)	
≥ 70 % (Normal)	9 (32 %)
< 70 % (Abnormal)	19 (68 %)
2. Variation coefficient (%) (38± 0.06)	
≤ 36 % (Normal)	11 (39 %)
> 36 % (Abnormal)	17 (61 %)
	Cases n=27
3. Total cholesterol (mg dL ⁻¹) (152.22 ± 28.10)	
≤ 200 mg dL ⁻¹ (Normal)	24 (89 %)
> 200 mg dL ⁻¹ (Abnormal)	3 (11 %)
4. HDL (mg dL ⁻¹) (55.65 ± 9.43)	
≥ 35 mg dL ⁻¹ (Normal)	27 (100 %)
< 35 mg dL ⁻¹ (Abnormal)	0 (0 %)
5. LDL-c (mg dL ⁻¹) (80.96 ± 18.11)	

≤ 130 mg dL ⁻¹ (Normal)	27 (100 %)
> 130 mg dL ⁻¹ (Abnormal)	0 (0 %)
6. Triglycerides (mg dL ⁻¹) (76.07 ± 51.06)	
≤ 170 mg dL ⁻¹ (Normal)	24 (89 %)
> 170 mg dL ⁻¹ (Anormal)	3 (11 %)
Vitamin D (ng mL ⁻¹) (21.85 ± 8.52)	
> 20 ng mL ⁻¹ (Normal)	14 (52 %)
12 - 20 ng mL ⁻¹ (insufficiency)	10 (37 %)
< 12 ng mL ⁻¹ (deficiency)	3 (11 %)

HbA1c Hemoglobin A1c or glycated hemoglo 1;HDL High-density;LDL Low-density lipoprotein, BMI body mass index;

Supplementary material

Table 4-dataset including demographic data, biochemical parameters, results of neurological examinations, and nerve conduction study values.

Sex (F=female M=male)	F	F	F	M	M	M	M	F	M	M	M	M	M	M	M	F	F	M	M	F	F	M	M	M	F	F	M	M	M
DMT1 duration (years)	15	14	14	12	13	15	16	14	10	14	13	12	10	8	13	12	10	15	13	11	14	6	16	13	12	8	8	10	5
Age (years)	17	17	16	17	14	15	17	15	16	15	16	14	12	15	16	14	14	16	15	15	15	12	17	17	17	12	15	16	18
Height (cm)	175, 5	158, 5	165	174, 2	162, 5	174, 6	172, 8	164, 8	174, 5	169, 4	182, 4	167	147, 7	185	170	162, 5	155, 5	172, 2	181, 8	159, 5	155	154	170, 3	187	172	160, 5	169, 5	172, 1	163, 5
Weight (Kg)	77,6	48	66,5	60	56,8	60,6	64,4	69,5	63,7	70	69,7	55,5	41,1	65,9	61,5	69,1	55,7	54,9	64,6	54,5	57,6	41,2	64,7	81,8	92,1	42,2	56,8	70,5	70,1
BMI (kg m ⁻²)	25,1 9	19,1 1	24,4 3	19,7 7	21,5 1	19,8 8	21,5 7	25,5 9	20,9 2	24,3 9	20,9 5	19,9 0	18,8 4	19,2 5	21,2 8	26,1 7	23,0 4	18,5 1	19,5 5	21,4 2	23,9 8	17,3 7	22,3 1	23,3 9	31,1 3	16,3 8	19,7 72	23,8 0	26,2 2
HbA1c (%)	9,1	7,5	6,7	7,4	7,4	5,5	7,9	8,9	7	7,2	8,3	6,9	8,4	6,3	9,8	6,5	6,5	6,5	6,3	7	7,1	7,1	6,6	8,1	8,4	6,8	8	11,2	7,1
Fasting plasma glucose (mg dL ⁻¹)	240	111	167	159	179	139	190	249	208	172	150	156	186	142	218	166	156	132	163	212	163	168	187	226	209	86	186	285	181
HDL (mg dL ⁻¹)	65	54	82	43	55	65	57	45	70	45	51	59	46	54		41	59	45	61	55	58	58	51	53	50	72	53	68	
Total cholesterol (mg dL ⁻¹)	230	134	205	135	162	203	172	146	171	125	155	165	142	120		120	125	101	139	125	175	149	154	137	144	163	152	161	
LDL (mg dL ⁻¹)	111	66	87	79	95	118	105	58	98	65	95	93	96	58		71	59	45	69	60	108	79	84	73	73	83	83	75	
Triglycerides (mg dL ⁻¹)	231	71	181	64	59	99	48	213	54	77	44	63	30	39		40	36	44	45	49	47	61	94	56	103	39	79	88	
25- oH- vitamin D total (ng mL ⁻¹)	38	11	19	18	20	26	39	16	13	21	13	25	15	12		20	7	21	25	10	19	33	29	34	21	30	22	33	
Urea (mg dL ⁻¹)	27	31	23	24	23	33	27	33	25	21	19	29	26	39	29	23	32	27	30	24	17	36	46	40	26	29	26	35	
Creatinine (mg dL ⁻¹)	0,7	0,7	0,67	0,75	0,58	0,63	0,77	0,53	0,74	0,58	0,79	0,56	0,4	0,6	0,42	0,6	0,49	0,77	0,51	0,48	0,69	0,53	0,96	0,97	0,69	0,68	0,7	0,88	
Albuminuria (mg L ⁻¹)	12,2	7,3	11,4	3,1	6,3	1,7	4,3	5,3	21,3	9	17,6	7,2	3,9	3,7	12,1	3,2	5,6	6,9	3,7	3,2	1,2	1,2	7,1	10,7	45,8	126, 8	9,5	1,6	
Albumin/ creatinine Ratio (mg g ⁻¹ creatinine)	6,7	7,3	4,8	1,4	2,7	1,5	11,5	10,6	8	3,7	8,9	6,5	4,3	3,4	9,5	2,2	3,7	2,9	2,6	3,5	6,6	1,2	2,6	6,8	23,3	48	4,3	1,6	
Time In Range (%)	29%	84%	72%	61%	49%	75%	46%	35%	65%	60%	43%	85%	48%	75%	14%	68%	74%	77%	67%	73%	63%	62%	70%		44%	69%	43%	15%	30%
Variation Coefficient (%)	41%	32%	30%	41%	51%	43%	43%	49%	34%	34%	38%	36%	46%	31%	36%	38%	30%	33%	37%	38%	35%	32%	33%		49%	39%	39%	38%	45%

Muscular atrophy (Presente=1 Absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ulcers(presente=1 Absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pateller reflex (normal =0 increased=1, decreased or absent =2)	0	0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	2	0	0	2	0	0	0	0	0	0	0	0
Bicipital Relfex (normal =0 increased=1 decreased or absent =2)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Tricipital Reflex (normal =0 increased=1 decreased or absent=2)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Achilles reflex (normal =0 increased=1 decreased or absent =2)	0	0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	2	0	0	2	0	0	0	0	0	0	0	0
Vibration (present =1 absent=0)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Cutaneous sensation (present=1 absent=0)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Muscular force- dorsiflexion (0-5)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Muscular force- plantar flexion (0- 5)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Muscular force- knee flexion (0- 5)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Muscular force- knee extension (0- 5)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Muscular force- elbow flexion (0-5)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
Muscular force- elbow extension (0-5)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
Burning sensation (present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Shock like sensation (present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Tingling (present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Numbness (present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
Cramps (present= 1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Fatigue (present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Instability while walking (present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Hyperalgesia(present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Allodynia (present=1 absent=0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Latency- left medianus motor (m s)	3,12	3,29	3,33	3,71	3,71	3,71	3,58	3,21	3,17	2,92	3,64	3,38	2,97	3,85	3,83	3,25	2,83	4,17	3,46	3,04	3,56	3,42	3,4	3,79	2,88	3,1	3,1	3,65	3,1
Amplitude-left medianus motor (m V)	9,5	8,1	7,4	11,4	6,5	8,2	7,8	6,4	10	11	11,8	6,3	5,4	11,5	7,2	8,5	9	9,6	6	10,7	5,5	6,3	8,9	8,6	7,5	12,8	8,3	7,9	7,2
Conduction velocity-left	56,8	60,7	56,5	59,7	50,1	50,8	54,7	55,6	55,3	55,4	65	56,4	57,1	55,8	54,7	59,7	57,6	58,7	60,4	58,8	53,9	65,5	59,3	56,2	50,3	57,6	57	55	55,6

medianus motor (m s ⁻¹)																																
Latency-Right medianus motor (m s)	3,42	2,81	3,38	3,73	3,46	3,88	3,6	3,42	3,44	2,98	3,6	3,42	2,94	4,23	3,46	3,17	3,02	3,69	3,15	3,15	3,98	3,46	3,19	3,69	3,29	2,81	3,13	3,69	3,06			
Amplitude-Right medianus motor (m V)	9,9	9,6	8,6	7,5	9,5	9,5	12,5	9,1	11,3	12,3	11	6,1	5,1	9,3	9,1	10,5	8,9	11,3	8,6	9,5	6,2	7,7	13,5	9,3	8,4	11,5	8,5	6,7	10,2			
Conduction velocity-Right medianus motor (m s ⁻¹)	57,2	58,4	59,4	53,9	59,3	58	59,9	51,7	58	55,3	57,3	60,1	66,9	55,8	57	60,1	59,2	59,1	58,5	57,1	54,5	60,5	58,7	58	56,7	58,5	58,0	55,1	60,3			
Latency-Left peroneus motor (m s)	5,17	3,25	4,29	4,25	4,46	4,9	4,79	3,33	4,25	3,9	4,06	3,91	3,65	4,4	4,6	4,1	3,17	4,33	5,17	4,27	3,16	3,98	3,83	4,69	4,06	3,99	3,83	3,81	3,65			
Amplitude-left peroneus motor (m V)	5,2	7,1	3,7	5,8	4	6,8	8,2	6,7	6,8	3	5,3	3,9	1,46	3,5	4,9	4,5	5,4	6,2	3,3	5,5	4	5	13,1	7,2	5,3	4,6	6,2	7	9,3			
Conduction velocity-Left peroneus motor (m s ⁻¹)	44	51,4	49,1	48,7	57,4	56,1	54,4	49,4	52,7	50,5	43,7	50,1	46,5	40,5	47,6	48,7	49,6	52,4	51,4	50,7	51	51,4	52	46,8	46,7	48,6	50,4	47,6	49,3			
Latency-right peroneus motor (m s)	4,33	3,1	3,69	3,48	3,6	3,65	3,63	3,32	3,85	3,58	4,68	3,54	3,81	4,23	3,67	4,19	3,77	4,27	3,92	4,38	3,85	3,97	3,44	3,65	3,73	3,67	3,37	4,13	3,48			
Amplitude-right peroneus motor (m V)	6,6	7,6	4,7	6,6	4,6	7,8	9,6	6,1	8,2	3,6	5,2	3,8	2,8	5,6	10,1	3,9	4,3	7,3	6,1	6,7	5,3	7,1	11	9,7	7,2	2,9	6,3	5,1	7,8			
Conduction velocity- right peroneus motor (m s ⁻¹)	43,7	53,3	47	47,7	49,7	46,9	53,5	53,6	50,3	47,6	47,9	47	52,5	40,4	44,4	47	54,7	48,9	48,6	50,9	48,3	51,5	50,6	44,1	45,8	47,7	50	47	51,3			
Latency-left ulnaris motor (m s)	2,48	2,46	2,48	2,62	2,6	2,85	2,92	2,56	2,3	2,6	3,13	2,44	2,38	3,21	2,42	2,31	1,96	3,23	2,35	2,56	2,44	2,42	2,6	2,9	2,23	2,25	2,42	2,63	2,52			
Amplitude-left ulnaris motor (m V)	8,9	9,7	8,3	8,6	7	9,9	10,6	8,1	7,7	6,8	9,7	10,3	7,4	7,7	7,5	8,7	8,9	9	7	9,1	7,7	7,3	10,9	10,5	7,9	9,6	9	11,3	6,7			
Conduction velocity-left ulnaris motor (m s ⁻¹)	53,2	67	58,8	68,4	56,8	59,2	60,8 9	58,6	63,5	68,6	59,1	57,1	70,4	61,2	58	63,5	66,1	56,9	64,1	60,3	56,7	61,6	59,6	61,6	52,3	60,7	59,8	57,7	67,1			

Latency-right ulnaris motor (m s)	2,73	2,38	2,69	2,52	2,83	2,38	3,23	2,71	2,69	2,44	3,25	2,67	2,46	3,25	2,58	2,65	2,06	3,04	2,38	2,65	2,9	2,56	3,21	2,52	2,48	2,27	2,44	2,6	2,5
Amplitude-right ulnaris motor (m V)	8,8	10,1	7,4	9	6,2	9,4	10,3	7,4	7,7	6,1	9,4	8,5	9,6	8,2	8,1	7,8	9	9,5	6,5	9,1	10,3	6,6	11,9	8,7	6,6	10,9	11,1	9,6	6,2
Conduction velocity-right ulnaris motor (m s ⁻¹)	65	65,7	56	68,6	56,9	56	57,1	53,6	60,1 2	63,3	56,1	65,3	70,9	55,7	54,5	63,8	60,4	51,3	66,7	60,3	62,3	61,7	64,5	56,7	51,3	60,4	59	59,3	61
Latency-left tibialis motor (m s)	4,98	4,13	4,09	3,25	3,87	3,63	4,58	4,62	3,44	3,82	3,16	4,35	3,92	4,32	3,99	3,7	3,68	5,23	4,44	3,92	5,04	4,51	3,65	4,08	3,43	3,75	4,13	4,85	4,76
Amplitude-left tibialis motor (m V)	7,8	12,2	6,3	17,3	6	9,7	11,5	9,5	10,2	5,8	11,1	9,7	10,1	9,1	13,7	11,1	16,4	11,1	15	9,8	16,8	14,7	23,1	9,5	10,6	11,4	9,3	9,8	11,8
Latency-left tibialis motor (m s)	4,79	3,33	4,14	4,58	3,83	3,75	4,9	4,17	4,96	3,54	5,13	3,92	3,23	4,9	4,45	3,32	3,73	4,96	4,94	4,24	4,08	3,7	4,46	3,62	4,35	4,54	4,63	3,92	4,73
Amplitude-Right tibialis motor (m V)	6,9	9,6	8,9	13,2	8,3	13,2	12,4	10,1	9,2	9,9	12,2	7,2	7,4	10,7	15,5	9,4	14,1	16,7	14	9,6	13,7	14,5	17,2	7,4	13,7	11,6	16,7	8,9	10,4
F minimal latency right (m s)	50,2	42,4	47,3	44,2	43,4	48,3	44,9	44,5	49,7	42,5	52,2	41,4	37,8	54,2	47,7	48	39,3	46,4	49	42,3	42,6	42,4	42,8	49,7	48,7	44,5	45,6	46,2	44
F minimal latency left (m s)	54,2	41,8	46,2	43,2	42,9	46,9	44,7	44,1	52,1	42,8	50,1	44,5	37,4	54,4	48,5	46,3	39,8	46,2	49,1	41,5	44,4	41,1	44,3	49,9	48,8	45,4	45,9	47,5	43,2

STATEMENT	TEXT
Acknowledgments	The authors acknowledge the technical help and support of the department of neurophysiology of ULS São João, namely Dr. Fernando Silveira and the department of pediatrics.
Research ethics	The study was approved by the Ethics committee of ULS São João, Porto and was conducted in accordance with the Declaration of Helsinki.
Informed consent	Informed consent was obtained from all individuals included in this study and their legal guardians or wards.
Author contributions	All authors have accepted responsibility for the entire content of this manuscript and approved its submission.
Use of Large Language Models, AI and Machine Learning Tools	None declared.
Conflict of interest	All other authors state no conflict of interest.
Research funding	None declared.
Data availability	Data available within the article or its supplementary materials.

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 7; Paragraph 2 “This is a cross-sectional study involving children aged 12 to 18 years who have been diagnosed with diabetes for five or more years and are receiving treatment with an insulin pump. “
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 7; Paragraphs 2 and 3 “All participants underwent a neurological examination and were questioned about symptoms of motor neuropathy. “ “A total of 29 children completed the study, with a mean age of 15.34 ± 1.56 years and a mean duration of diabetes of 11.93 ± 2.84 years. HbA1c levels were 7.50 ± 1.1 %. “ “Results were normal, indicating adequate motor nerve integration and excluding the presence of motor neuropathy and any evidence of diabetic polyneuropathy, even at subclinical level.”
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 10; Paragraphs 6 and 7 “Multiple studies using nerve conduction tests (NCS) have shown the ability to detect subclinical motor involvement, revealing reduced motor nerve conduction velocity (MNCV) and amplitude, indicative of nerve deterioration.” “Studies emphasize the importance of NCS in detecting early motor dysfunction, revealing a high prevalence of subclinical neuropathy in diabetic patients and indicating that motor involvement is more frequent than previously recognised”
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 11; Paragraphs 1 and 4 “These findings substantiate the hypothesis that NCSs provide significant advantages for early screening and detection of motor neuropathy. By identifying nerve dysfunction before clinical symptoms emerge, these tests enable earlier interventions, potentially slowing progression and preventing severe motor complications” “The main objective is to evaluate the point prevalence of motor neuropathy in children and adolescents with a 5-year or more diagnosis of type 1 diabetes using nerve conduction studies. We will analyse various biochemical and clinical parameters of each individual to evaluate their metabolic control. Subsequently, to potentially

			identify factors that may increase the risk of developing motor neuropathy, we intend to evaluate positive motor neuropathy diagnoses with these parameters.”
Methods			
Study design	4	Present key elements of study design early in the paper	Page 12; Paragraphs 1, 2 and 5 “This cross-sectional analytical study was conducted at the paediatric endocrinology department of the Centro Hospitalar Universitário S. João(CHUSJ), from September 2024 to March 2025.” “We reviewed all the children who attended the semester evaluation consultation for their Type 1 Diabetes Mellitus (T1DM) diagnosis between September 2024 and January 2025. Among them, we found a total of 42 children who met our inclusion criteria: they were aged between 10 and 18 years, had been diagnosed with T1DM for over five years, and were being treated with an insulin pump” “The enrolled children underwent a standardized and systematic summary neurological examination which included ankle, patellar, bicipital and tricipital reflex, assessment of muscular force, vibration and cutaneous sensation.” Page 13; Paragraphs 3 and 5 “Following the neurological summary examination, participants were inquired about the presence of various symptoms suggestive of neuropathy, including cramps, numbness, tingling, burning sensations, electric shock-like sensations, instability while walking, fatigue, hyperalgesia, and allodynia.” “Motor conduction studies were performed bilaterally on the median, ulnar, common peroneal, and posterior tibial nerves” Page 14; Paragraph 1 “Needle electromyography (EMG) was conducted on all individuals for the right peroneus tertius and right vastus medialis, as this test shows greater sensitivity for axonal motor damage”
Setting	5	Describe the setting, locations, and relevant dates, including periods of	Page 12; Paragraphs 1 and 2 “This cross-sectional analytical study was conducted at the paediatric endocrinology

		recruitment, exposure, follow-up, and data collection	department of the Centro Hospitalar Universitário S. João(CHUSJ)), from September 2024 to March 2025. “ We reviewed all the children who attended the semester evaluation consultation for their Type I Diabetes Mellitus (T1DM) diagnosis between September 2024 and January 2025.”
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	Page 12; Paragraphs 2 and 3 “We reviewed all the children who attended the semester evaluation consultation for their Type I Diabetes Mellitus (T1DM) diagnosis between September 2024 and January 2025. Among them, we found a total of 42 children who met our inclusion criteria: they were aged between 10 and 18 years, had been diagnosed with T1DM for over five years, and were being treated with an insulin pump. “
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 13; Paragraphs 4 and 5 “ F minimal latency (ms) was considered normal if equal to or lower than 55. “ “Table 3 shows the reference cut-off values considered normal and routinely used in clinical practice” Page 14; Paragraph 1-3 “Needle electromyography (EMG) was conducted on all individuals for the right peroneus tertius and right vastus medialis, as this test shows greater sensitivity for axonal motor damage.” “Data were collected and analysed, including age, gender, height, weight, body mass index (BMI), duration of diabetes, haemoglobin A1c (HbA1c), fasting plasma glucose, lipid profile (HDL, LDL, total cholesterol, triglycerides), time in range (TIR) percentage, coefficient of variation, vitamin D levels, urea, creatinine, albuminuria and the spot albumin-to-creatinine ratio. “
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 12; Paragraphs 6 and 7 “Vibration was evaluated using a 128 Hz tuning fork placed on the dorsum of the great toe, just proximal to the nail bed. “ Page 13 “The assessment of muscular force involved extending and flexing the ankle, knee, and elbow, which was then graded using the Medical Research Council (MRC) scale from 0 to 5. “

			“The reflexes were evaluated using a reflex hammer and scored as normal (=0), present with reinforcement (=1) or absent (=2). “ “Following the neurological summary examination, participants were inquired about the presence of various symptoms, including cramps, numbness, tingling, burning sensations, electric shock-like sensations, instability while walking, fatigue, hyperalgesia, and allodynia. “ “F minimal latency (ms) was considered normal if equal to or lower than 55. “ “Table 2 shows the reference cut-off values considered normal and routinely used in clinical practice.” Page 14; Paragraph 1 Needle electromyography (EMG) was conducted on all individuals for the right peroneus tertius and right vastus medialis, as this test shows greater sensitivity for axonal motor damage.”
Bias	9	Describe any efforts to address potential sources of bias	Page 12; Paragraph 5 “All evaluations were conducted by a single individual to eliminate interobserver bias, thereby reducing variability in the application and interpretation of the neurological examination.” Page 13; Paragraph 4 “The electrophysiological test was done by the dantec keypoint electromyography machine by a single neurophysiologist who was blinded to the patient’s clinical and medical history. “
Study size	10	Explain how the study size was arrived at	Page 12; Paragraph 3 “The total number of participants was determined based on a review of similar studies, the total number of children monitored at CHUSJ, and practical considerations such as time constraints and the availability required to conduct both NCS and neurological examinations.”
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 14; Paragraph 4 “Data are presented as arithmetic means with standard deviations”
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	No statistical method was made because all NCS and EMG results were normal.

		(b) Describe any methods used to examine subgroups and interactions	No subgroup analysis was made.
		(c) Explain how missing data were addressed	Page 14; Paragraph 4 “After confirming that they followed a normal distribution, the mean was used to impute these missing values. This approach was employed to preserve the data size and avoid removing three individuals from the analysis.”
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable.
		(e) Describe any sensitivity analyses	Without the application of statistical analysis, there were no variable data points or alternative assumptions to tests.
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 15; Paragraphs 1 and 2 “Out of the 42 individuals assessed for eligibility, 2 were initially excluded from the study: one had Charcot-Marie-Tooth syndrome, and the other had a cognitive disorder. Additionally, 3 individuals declined to participate. Ultimately, a total of 29 participants completed the study. Of the 37 individuals who initially agreed to participate, a total of 8 did not attend the scheduled electromyography session.”
		(b) Give reasons for non-participation at each stage	Page 15; Paragraph 2 “Some individuals gave no reason for their absence, while others were hesitant to miss classes solely for the purpose of the exam.”
		(c) Consider use of a flow diagram	Page 22; Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 15; Paragraph 3 “The mean age of the patients was 15.34 ± 1.56 y, 34.48% were female and 65.52% were male. The mean age duration of T1DM was 11.93 ± 2.84 . The biochemical characteristics of the patients are shown in Table 3.”
		(b) Indicate number of participants with missing data for each variable of interest	Page 14; Paragraph 4 Page 25-29 table 4 “Data are presented as arithmetic means $\pm$ standard deviations. Three missing conduction velocity values (highlighted in orange in Table 4) were imputed using the mean after confirming a normal distribution.”
Outcome data	15*	Report numbers of outcome events or summary measures	Page 15; table 1

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	This study did not perform statistical analyses; therefore, unadjusted and confounder-adjusted estimates, as well as their precision (e.g., 95% confidence intervals), are not provided.
		(b) Report category boundaries when continuous variables were categorized	Page 14; Paragraph 3 “Metabolic control was considered good if HbA1c levels were between 6.5 and 7.5%, moderate if between 7.6 and 9.0% and poor if above 9.0%” Page 23 and 24 Table 3
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No other analysis was done.
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 16; Paragraph 2 “Our study found no evidence of subclinical motor neuropathy in any of the participants, suggesting that motor nerve function remained preserved in this population. “
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 18; Paragraphs 3-5 “Some factors may limit the study’s generalisability. It was conducted in a single centre, CHUSJ, a hospital with experienced physicians and systematic treatment monitoring. This may not fully represent the broader paediatric T1DM population in other hospitals. This study may be subject to some healthy user bias, as some children or adolescents who did not participate in the electromyography had poorer metabolic control and appeared to be less concerned about their health. “
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 16; Paragraphs 2 and 3 “Abuelwafaa et al. 2019 studied 50 diabetic patients aged 10-18 years and found that 88% had electrophysiological evidence of peripheral neuropathy, primarily affecting motor function (68.2%) with no cases of pure sensory neuropathy.”

			“Singh et al. 2022 study, out of also 50 children aged 8-18 years, 56% exhibiting subclinical neuropathy on NCS, with 40% having pure motor, 2% pure sensory, and 14% mixed motor-sensory neuropathy.” Page 17; Paragraphs 1-3 “On the other hand, Walter-Holiner et al.2018 conducted a cohort study with a 5-year follow-up, in Austria with a total of 38 patients aged 9-18 years.” “There were one or two individual measurements that were close to the reference range, particularly the common peroneal nerve velocity and F minimum latency” “ In instances of isolated borderline values, it is crucial to consider the broader context, potential concomitant alterations like altered tibial F waves, altered needle electromyography, clinical symptoms, changes in physical neurological exam and the individual's height. For these individuals, a follow-up evaluation is recommended within a five-year period to determine whether there have been any significant changes in the values compared to the initial assessment.”
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 18; Paragraphs 1 and 3 “Consistent and reliable results were achieved through standardized neurological and electrophysiological assessments, which offered a comprehensive and objective evaluation of neuropathy in patients with T1DM. This also ensured comparability across different settings and populations” “Some factors may limit the study’s generalisability”
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	“No sources of funding”

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at

<http://www.annals.org/>, and *Epidemiology* at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

Journal of Pediatric Endocrinology and Metabolism



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Scope and general policies of the journal

Scope

The *Journal of Pediatric Endocrinology and Metabolism (JPEM)* is the official journal of the [German Society of Pediatric and Adolescent Endocrinology and Diabetology \(DGPAED\)](#). *JPEM* is a peer-reviewed journal that publishes cutting-edge articles on clinical investigations in pediatric endocrinology, diabetes, inherited metabolic disorders, metabolism and translational research. *JPEM* is an international journal devoted exclusively to endocrinology in the neonatal, pediatric and adolescent age groups. *JPEM* is a high-quality journal dedicated to pediatric endocrinology, diabetes and metabolic diseases in its broadest sense, including research on epidemiology, pathophysiology, multidisciplinary management and technology, filling a gap at a time of rapid expansion in the field.

JPEM is a hybrid journal, published monthly in print and online. All contributions submitted for publication in *JPEM* are subject to single-anonymized peer review by at least two experts in the field, selected and invited by the Editor-in-Chief and a dedicated Editorial Team. *JPEM* publishes only English-language articles in the categories listed below.

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- Original Article – Reports of original research
- Review and Mini Review – Systematic, narrative, and focused reviews
- Opinion Paper
- Perspectives
- Editorial
- Case Report
- Case Report and Review of the Literature
- Short Communication
- Letter to the Editor and Reply
- Guidelines and Recommendations
- Congress Abstracts

Submissions in the following fields are welcome

- Pediatric Endocrinology
- Pediatric Diabetes
- Pediatric Obesity
- Inherited Metabolic Diseases
- Neonates/Neonatal Screening
- Hormonal Disorders and Therapy
- Adrenal Disorders
- Pituitary Disorders
- Thyroid Disorders
- Disorders of Bone, Calcium and Vitamin D Metabolism
- Growth Disorders
- Endocrine Cancers
- Disorders of Gonads and Puberty
- Disorders of Sex Differentiation and Gender Dysphoria
- Psychosocial Aspects of Chronic Conditions in Pediatric Endocrinology and Diabetology
- Multidisciplinary Care for Children and Their Families

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JPEM publishes special issues and special issue sections focused on important and emerging topics in the field of study. Ideas for special issues and special issue sections are proposed by the journal's editorial board, but the journal will also consider proposals for special issues submitted by members of the wider research community. All proposals are assessed for quality and relevance by the Editor-in-Chief and the editorial office.

The journal has established a rigorous process to ensure that all manuscripts submitted for special issues follow the same high-quality standards and peer review process as regular manuscripts. Each special issue has a dedicated Guest Editor who is responsible for the coordinating the peer review process of all manuscripts submitted

for the special issue (section). The Editor-in-Chief checks the initial manuscript and assigns it to the appropriate Guest Editor. The Guest Editor invites reviewers and makes recommendations on revisions and final decisions. The Editor-in-Chief has an oversight of the entire process within the online submission system and is responsible for the final decision on all manuscripts.

Submission of manuscripts

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Scientific misconduct

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The authors are responsible for all aspects of the study and will ensure that any questions regarding the accuracy and integrity of any part of the work are adequately investigated and resolved.

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technologies are used as part of the design or methodology of a research study, please specify the tool and the purpose of its use for the conducted research in the Methods section of your manuscript, and if applicable indicate the use of Large Language Models, AI and Machine Learning Tools for manuscript preparation in the [Template for Ethical and Legal Declarations](#). In case of doubt, the Editorial Board reserves the right to ask the authors to submit the raw experimental data.

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JPEM requires authors to follow our [Data Sharing Policy](#), which must comply with the European GDPR (*General Data Protection Regulation*) rules.

Research data should be made widely available to the research community to demonstrate the robustness and validity of the research presented in the journal, to enable and encourage replication of the results, and to allow the community with opportunities to learn.

We recommend the use of community-endorsed data types. If you assign a persistent identifier to your research data by archiving it in a data repository, other researchers will be able to cite your data as well as your published research article.

Where possible, data should be submitted to discipline-specific, community-recognized repositories. In cases where there is no appropriate discipline-specific resource, data may be submitted to a general data repository. Please see <https://www.re3data.org/>, <https://fairsharing.org/>, or <https://repositoryfinder.datacite.org/> for help finding research data repositories. We strongly recommend using [CoreTrustSeal](#) certified repositories.

To determine whether a research data availability statement is required and what format it must follow, please refer to the specific file for each policy level available on the [Data Sharing Policy](#) website. Detailed information can be found in the “Submit” tab on the journal website.

Please fill in your statement on data availability in the [Template for Ethical and Legal Declarations](#), which is required for submission.

We further recommend citing the data that has been shared in the reference list. Data citations should include a persistent identifier, should be included in the reference list using the minimum information recommended by [DataCite](#) (Dataset Creator, Dataset Title, Publisher [repository], Publication Year, Identifier [e.g. DOI, Handle or ARK]) and follow journal style.

Peer review, turnaround times and pre-publication policies

Rejection of manuscripts

Submitted manuscripts will be reviewed in a two-step procedure. Firstly, the Editor-in-Chief decides whether the manuscript fulfills the substantive and formal criteria for the further peer review process. The decision is based on the following criteria:

- relevance: the content conforms to the scope and goals of *JPEM*,
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- formal correctness: the formal criteria have been met (also in view of the manuscript being written in understandable English),
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Standards

18. Frequency response and bias, NERC Reliability Standard BAL-003-0.1b, May 2009 [Online]. Available from: http://www.nerc.com/files/BAL-003-0_1b.pdf

Corporate publication

3. WHO. The diagnosis and management of non-alcoholic fatty liver disease: practice guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association. *Hepatology* 2012;55:2005–23.

General format and length of article types accepted for submission

(JPEM) Word count: title page, abstract, tables, figures, references, abbreviations, appendices & supplementary material are excluded.

	Word count	Word count in abstract	Number of keywords	Number of Tables & Figures	Number of references	Article
Original Article	3500	250, structured <i>Objectives, Methods, Results and Conclusions</i>	3–6	8	50	Structured into Introduction, Materials (Subjects) and methods, Results, Discussion, (Limitations), (Strength), (Conclusions)
Review	6000	200, unstructured/ structured <i>Background, Content, Summary and Outlook</i>	3–6	8	150	Structured
Mini Review	3500	200, unstructured/ Structured <i>Background, Content, Summary and Outlook</i>	3–6	4	40	Structured
Opinion Paper	3500	250, unstructured/ Structured <i>Background, Content, Summary and Outlook</i>	3–6	2	40	Structured
Point & Counterpoint	1500	200, unstructured	3–6	2	15	Structured or unstructured
Letter to the Editor & Reply	1200	n/a	3–6	2	10	Unstructured
Guidelines and Recommendations	3500	250, unstructured	3–6	6	40	Structured
Editorial	1500	n/a	n/a	1	10	Structured or unstructured
Short Communication	1500	200, structured <i>Objectives, Methods, Results and Conclusions</i>	3–6	2	15	Abstract & Introduction, Materials (Subjects) and methods, Results, Discussion
Case Report	3500	200, structured <i>Objectives, Case presentation and Conclusions</i>	3–6	6	40	Structured into Introduction, Case presentation, Discussion, (Conclusions), Learning points, What is new?

Case Report and Review of the Literature	4000	200, structured <i>Objectives, Case presentation and Conclusions</i>	3-6	6	50	Structured into Introduction, Case presentation, Methods (literature search), Discussion, Conclusions, Learning points, What is new?
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Please note the following points when submitting your work

- You have read the Instructions for Authors [Instructions for Authors](#)
- The manuscript is complete and uploaded correctly as Word file (or LaTeX). The HTML version and/or the PDF file generated from the submitted files must be complete and approved.
- The language in which the manuscript was written is correct and has been checked by a native speaker or a professional language service, if applicable.
- The title page information includes the full title, short title (both down style (non-capitalized, except for the first word and any proper name), the full names of all authors (given name, middle initials, family name), and the full address, affiliation and the academic title of the corresponding author. The title page should also indicate the word count, the number of tables and figures, and whether the submission includes any supplementary material.
- All figures and tables have been uploaded and appear correctly at the end of the generated PDF.
- Abstract, keywords, list of abbreviations, tables and figures, and captions and legends are included, depending on the manuscript type.
- Manuscript is spell-checked and within the word limit for the type of article.
- References are in the correct format according to the Instructions for Authors.
- References mentioned in the reference list are cited in the text and vice versa.
- Please check the data sharing policy stated in the Instructions for Authors and in the ["Submit"](#) tab on the journal website. Authors are required to provide a data availability statement.

[Template for Ethical and Legal Declarations](#)

- Strictly adhere to the instructions and wording of the template.
- The information in the Template must be identical with the information in the manuscript.
- **Only the information contained in the template will be published in your article.**

Additional general layout guidelines

- ☐ **Fonts:** Italic font style is restricted to genes and Latin terms (except for abbreviations such as e.g., et al.).
- ☐ **Numbers:** Written out in words up to ten and unless they are used as a unit of measurement or when used at the beginning of a sentence. This does not apply for figures and tables. Use decimal points, not commas. Write symbols, mathematical signs and their respective value without spaces (e.g n=1).

- **Manufacturer details:** Are to be provided incl. city and country for reagents and apparatus reported in the manuscript (use only USA and UK for United States and United Kingdom. For USA, sole use of the abbreviated state name is allowed). Use the correct symbol (e.g. ©, ®) and not the letters "TM" in superscript.
- **Abbreviations:** Both in the abstract and in the main text, abbreviations are to be spelled out at first mention. Thereafter, only these abbreviations are to be used. It is not necessary to include a list of abbreviations.
- **Learning points:** Are allowed (with En-dash) only for Case Reports, should be set before **What is new?**.
- **What is new?:** Are allowed (with En-dash) only for Case Reports, should be set before References.
- **References:** References should be listed at the end of the manuscript. **Adhere strictly** to the reference style of the Journal (Vancouver; recommendations of the [BioMedical Editor](#))
All references mentioned in the reference list have to be cited in the text and vice versa. List and number the references consecutively in the order they appear in the text, including Tables and Figures. In the text, identify references by Arabic numerals in [parentheses]. Italic and boldface font type is not allowed in the reference section. List all authors; if the number is 7 or more, list the first 6 names followed by et al. Identify authors by last name first, followed by up to 2 initials, without periods, indicating the authors' first name. Only the first name of the title is capitalized, as well as proper names within the title. Journal names are abbreviated as indicated in PubMed and in the Web of Knowledge ([NIH.Linkout.Journals](#); [Web of Knowledge](#)), without periods. After the abbreviated journal name, give the year of publication, followed by a semicolon, volume number (but no issue number), followed by a double colon, and the page numbers, with the last page number in shortened format. Meeting abstracts may be cited only if published in journals. Unpublished observations and personal communications are cited only in the text. Correct linking of the references depends on strict adherence to journal style.
- **Equations:** Are to be numbered (Arabic numerals within parentheses in sequential order). In-text citation format: Eq. (1); Ranges: Eqs. (1)–(5); Eqs. (1) and (4). Simple maths should be converted into text.
- **Variables:** Greek lowercase: Roman; Greek uppercase: Roman; Single letter variables: Italics; Multi-letter variables: Roman preferred.
- **Units:** All units should be in Roman. Unit separation should be comma in table entries. Spaces should be presented between numbers and units (except for %). Units are to be expanded with numbers and units if beginning a sentence.
 - Degree Celsius; °C; should be spaced with non-breakable space.
 - Liter should be capitalized in all combinations of liter units (L/mL/dL.....).
 - Molar 'M' should be caps. Units need not be repeated in value ranges.
 - P (referring to a population proportion) and p (to a sample proportion) are to be written in Roman. In table headers, 'p' should be written 'p-Value'.
 - Number is a lowercase n. n (to population and sample size) is to be written in Roman.
 - Volume and weight units should be abbreviated as 'vol' and 'wt' in unit–value combinations.
 - The coefficient of determination (R^2) is written in Roman with superscript 2.

- ☐ Use periods for the non-SI units:
inches → in.
atomic → at.
number → no.
as these abbreviations could be confused with the words in, at, and no.
- ☐ Centrifugation 'g' should be italics (either written with non-breakable space 1000 g or closed up with multiplication sign 1000×g) .
- ☐ Closed-up number and multiplication sign '×' for magnifications.
- ☐ Time unit abbreviations to be used: second – s; minute – min; hour – h; day – day/days; week – week/weeks; month – month/months; year – year/years.
- ☐ **Binominals:** Are written in italics.
- ☐ **Latin terms:** Should be italics but not in the Reference list (in vitro, in vivo, de novo, in situ, ad libitum...). Abbreviations of Latin terms should be Roman. (i.e., e.g., vs., et al...). 'Versus' should be written 'vs.' and in Roman font.

04 de Setembro de 2024

A Diretora do Centro de Epidemiologia Hospitalar

(Prof.ª Doutora Ana Azevedo)



SÃO JOÃO

n.º 104/2024

PEDIDO DE AUTORIZAÇÃO

Realização de Investigação

Deliberado e concordar, nos termos legais em vigor.

Exmo(a). Senhor(a) Presidente do Conselho de Administração do Centro Hospitalar Universitário de São João

CONSELHO DE ADMINISTRAÇÃO DA ULS SÃO JOÃO, EPE - REUNIÃO DE
Presidente do Conselho de Administração 17 SET. 2024

Nome do Investigador Principal:

Joana Helena de Bourbon Faria Ribeiro Lopes

Título da Investigação:

Rastreio de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1.

Diretora Clínica para a
área dos cuidados de
saúde hospitalares

Dra. Elisabete Barbosa

(Prof.ª Doutora Maria João Baptista)

Diretora Clínica para a
área dos cuidados de
saúde primários

Dra. Ligia Silva

Enfermeiro
DiretorEnf.ª Paulo Emilio
MotaVogal
ExecutivaDra. Fernanda
OliveiraVogal
ExecutivoDr. Vitor
LeitePretendendo realizar no(s) Serviço(s) de:
Pediatria

a investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efetivação.

Para o efeito, anexo toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar Universitário de São João respeitante à investigação, à qual enderecei pedido de apreciação e parecer.

Com os melhores cumprimentos.

Porto, 24 de Fevereiro de 2024.

O Investigador/Promotor

Assinado por: JOANA HELENA DE BOURBON FARIA RIBEIRO LOPES
Num. de Identificação: 14731777
Data: 2024.02.24 12:05:06+00'00'

assinatura



SÃO JOÃO

Encarregado
de Proteção de Dados
Data Protection Officer

Entrada

19.05.2024



CARTÃO DE CIDADÃO

Centro Hospitalar São João
Centro de Epidemiologia Hospitalar

13.7.2024

Parecer da Comissão de Ética do
Centro Hospitalar Universitário de São João

Título do Projeto: Rastreio de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1

Nome da Investigadora Principal: Joana Helena de Bourbon Faria Ribeiro Lopes, estudante do 6º ano do MIMED da FMUP. Serão co-investigadoras a Prof.^a Doutora Cíntia Gonçalves de Castro Correia e a Dra. Jacinta Rodrigues Fonseca. De acordo com o protocolo enviado à CE, e ao tipo de intervenção, deverá ser uma das co-investigadoras a assumir o estudo como investigadora principal, nomeadamente na abordagem a ser feita aos participantes.

Onde decorre o Estudo: No Serviço de Pediatria Médica do CHUSJ. Apresentou a declaração da Dra. Eunice Trindade. Questiona-se a necessidade de incluir a declaração de Neurofisiologia.

Objetivos do Estudo:

Este projeto tem como objetivo primário avaliar a prevalência de neuropatia motora em crianças e adolescentes com Diabetes Mellitus tipo 1. Será realizado uma eletromiografia em crianças e ou adolescentes com mais de 10 de idade, diagnosticadas há mais de 5 anos e que realizam tratamento com bomba infusora de insulina com intuito de realizar uma caracterização eletrofisiológica e identificar possíveis padrões de envolvimento motor. Á posteriori irá ser analisado se há uma associação entre os resultados da eletromiografia e alguns parâmetros clínicos e bioquímicos das crianças que, poderão ou não aumentar o risco de neuropatia diabética motora.

Estudo realizado no âmbito do Mestrado Integrado em Medicina da FMUP, sob orientação da Prof.^a Doutora Cíntia Gonçalves de Castro Correia.

Conceção e Pertinência do estudo:

O estudo é pertinente e adequado, porquanto consta no protocolo submetido à CE: "Os sinais e sintomas de neuropatia motora não são facilmente observados e detetados nas crianças com DMT1 com os atuais métodos de rastreio preconizados na pratica clínica, tendo consequenciais negativas e irreversíveis. Sabe-se que o rastreio é recomendado mas ainda não há diretrizes muito claras e eficazes. O diagnóstico atempado é extremamente importante para reduzir as consequências. Com este estudo pretende-se avaliar a prevalência de neuropatia motora e analisar o possível benefício da utilização da eletromiografia na deteção precoce de neuropatia motora periférica, numa fase subclínica da doença. Pretende-se também classificar melhor possíveis fatores de risco para o desenvolvimento desta patologia tornando mais aptos e com mais conhecimento para no futuro criar métodos de rastreio mais eficazes e eficientes, melhorando a capacidade de diagnóstico precoce".

Trata-se de um estudo cross-seccional com um tamanho da amostra estimado de 50 doentes, com mais de 10 anos de idade e mais de 5 anos de evolução da doença e seguidos na Consulta de Endócrino e Doenças Metabólicas de Pediatria do CHUSJ. Se idade dos 12 aos 15 anos deverá ser previsto o assentimento por parte do menor, com uma informação adequada à faixa etária.

Estão definidos os critérios de inclusão e as variáveis a recolher: dados demográficos (idade, sexo), duração DMT1, medicação, peso, altura, circunferência da cintura, resultados de análises (HbA1c, glicose, HDL, LDL, triglicerídeos, vitamina D, função renal, análise sumaria da urina), TIR (Time In Range) e Coeficiente de variabilidade e Glicose média, Exame físico e neurológico, Avaliação de sintomas (Ardor/queimadura,

Choques, picadelas, dor neuropática, Dormência, caíbra, Formigueiros, Fadiga, Instabilidade a caminhar, Hiperalgesia ou Alodinia).

Sendo um exame complementar de diagnóstico realizado para além dos inerentes à rotina assistencial, questiona-se de que forma está previsto o seu financiamento. Será de esperar que com 5 anos de evolução da doença esteja presente neuropatia?

Benefício/risco:

Espera-se que possa contribuir para uma deteção precoce de neuropatia motora periférica numa fase subclínica diminuindo as suas consequências negativas.

Como incómodos estima-se que possa existir um certo transtorno relacionado com a perda de tempo de vida pessoal na realização da eletromiografia, e também o envolvimento psicológico durante a realização do exame (devido ao possível diagnóstico precoce de neuropatia motora de DMT1).

Confidencialidade dos dados:

A pseudonimização será garantida através da substituição de informações identificáveis por identificadores únicos, como códigos alfanuméricos, de modo que os dados não possam ser facilmente relacionados a indivíduos específicos sem informações adicionais.

Apresentou um pedido de reutilização de registos clínicos para Investigação e Desenvolvimento ao RAI, e uma 'avaliação sobre o impacto da proteção de dados' para o EPD.

Respeito pela liberdade e autonomia do sujeito de ensaio:

Dispõe de uma adequada informação ao participante e modelo de CI do CHUSJ.

Curriculum da investigadora: Adequado à investigação.

Data previsível da conclusão do estudo: novembro de 2024

Conclusão: Deverá ser alterado o investigador principal, e responder às questões assinaladas, para que a CE se possa pronunciar sobre o protocolo em análise.

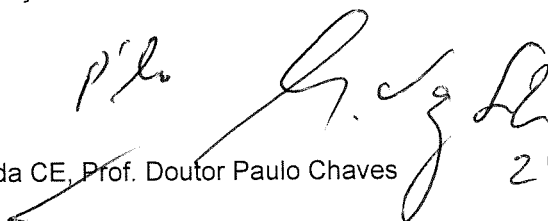
Porto, 22 de março de 2024

O Relator da CE, Prof. Doutor Paulo Chaves

Conclusão: Foi alterado o investigador principal, de acordo com o parecer inicial, passando a assumir o estudo a Dra. Jacinta Rodrigues Fonseca. Entregou a declaração da Unidade de Neurofisiologia. Entregou uma informação adequada aos participantes entre os 12-15 anos. Os esclarecimentos apresentados são suficientes. Proponho um parecer favorável à realização do estudo.

Porto, 24 de maio de 2024

O Relator da CE, Prof. Doutor Paulo Chaves


24/5/2024



SÃO JOÃO

SUBMISSÃO DE PROJETO DE INVESTIGAÇÃO PARA PARECER E AUTORIZAÇÃO

Preenchimento em formato digital obrigatório

Caro/a Investigador/a

Este questionário vai ser objeto de apreciação pela Comissão de Ética (CE), que emitirá o competente parecer; pelo Responsável de Acesso à Informação (RAI), que emitirá um despacho de autorização ou indeferimento, relativamente à reutilização da informação a que pretende ter acesso; pelo Encarregado de Proteção de Dados (EPD), que emitirá um parecer, mediante a 'avaliação do impacto sobre a proteção de dados' (que deve anexar a este pedido); pelo Centro de Epidemiologia Hospitalar; sendo enviado, num último momento, para decisão institucional do Conselho de Administração do CHUSJ. Os respetivos despachos de parecer e autorização serão exarados no final deste documento, e enviados posteriormente, de modo a poder iniciar, nesse momento, a investigação a que se propõe.

IDENTIFICAÇÃO DO ESTUDO

Título do projeto:

Rastreio de Neuropatia Motora em Crianças e Adolescentes com Diabetes Mellitus tipo 1

Data prevista para início: 1 / 4 / 24

Data prevista para o término: 30 / 11 / 24

EQUIPA DE INVESTIGAÇÃO

1. Investigador principal

Nome: Joana Helena de Bourbon Faria Ribeiro Lopes

Afiliação institucional: ☐ CHUSJ ☒ FMUP Outro: _____

Serviço/ Departamento: _____

Grupo profissional: _____ Cédula Profissional n.º: _____

Contacto telefónico: 926668035 Endereço eletrónico institucional: up201908122@up.pt

Formação em Boas Práticas Clínicas (GCP): ☒ Não ☐ Sim

2. Co-investigadores

Nome: Cíntia Gonçalves de Castro Correia

Afiliação institucional: Assistente Hospitalar Graduada

Grupo profissional: Assistente Hospitalar Cédula Profissional n.º: 35947

Contacto telefónico: 910006244 Endereço eletrónico institucional: u002720@ulssjoao.min-saude.pt

Nome: Jacinta Rodrigues Fonseca

Afiliação institucional: Assistente Hospitalar

Grupo profissional: Assistente Hospitalar Cédula Profissional n.º: 51295

Contacto telefónico: 914314972 Endereço eletrónico institucional: u013212@ulssjoao.min-saude.pt

(acrescentar n.º de investigadores, se apropriado ao projeto de investigação)

3. Promotor (se aplicável): _____

CARACTERIZAÇÃO DA INVESTIGAÇÃO

1. Metodologia da investigação

☐ Qualitativa ☒ Mista (qualitativa+quantitativa) ☐ Outra. Qual? _____

Se quantitativa:

☐ Experimental ☒ Observacional ☐ Sem intervenção ☒ Com intervenção

Se experimental ou observacional com intervenção, qual o tipo de intervenção?

☒ Algoritmo de decisão diagnóstica/terapêutica ☐ Comunicação

☐ Outra. Qual? _____

2. Aleatorização dos braços de intervenção: ☐ Não ☐ Sim

3. Se observacional, qual o desenho?

☐ Coorte prospetivo ☐ Coorte retrospectivo ☐ Caso-controlo

☒ Transversal ☐ Ecológico ☐ Outro. Qual? _____

REALIZAÇÃO DA INVESTIGAÇÃO

Local onde se realiza a investigação: ☒ CHUSJ ☐ FMUP ☐ Outro

Serviço/Departamento: Pediatria

Existem outros Centros onde se realizará a investigação? ☒ Não ☐ Sim. Quais? _____

ENTIDADE(S) QUE TUTELA(M) A INVESTIGAÇÃO

1. CHUSJ – Serviço: Pediatria

2. FMUP – Departamento: Ginecologia, Obstetrícia e Pediatria

3. Outra instituição. Qual? _____

ORIENTADOR (se aplicável)

Nome: Cíntia Gonçalves de Castro Correia

Afiliação: Assistente Hospitalar Endereço eletrónico institucional: u013212@ulssjoao.min-saude.pt

PROFISSIONAL DE LIGAÇÃO (se aplicável - ver anexo)

Nome: _____ Serviço: _____

ENQUADRAMENTO DA INVESTIGAÇÃO

Em trabalho académico? ☐ Não ☒ Sim Conferidor de grau? ☐ Não ☒ Sim

Síntese dos objetivos:

Este projeto tem como objetivo primário avaliar a prevalência de neuropatia motora em crianças e adolescentes com Diabetes Melitus tipo 1. Será realizado uma eletromiografia em crianças e ou adolescentes com mais de 10 de idade, diagnosticadas há mais de 5 anos e que realizam tratamento com bomba infusora de insulina com intuito de realizar uma caracterização eletrofisiologica e identificar possíveis padrões de envolvimento motor. Á posteriori iremos analisar se há uma associação entre os resultados da eletromiografia e alguns parâmetros clínicos e bioquímicos das crianças que, poderão ou não aumentar o risco de neuropatia diabética motora.

Fundamentação ética (incluir informação sumária sobre o estado da arte, ganhos em conhecimento/ inovação, ponderação geral sobre benefícios/risco):

Os sinais e sintomas de neuropatia motora não são facilmente observados e detetados nas crianças com DMT1 com os atuais métodos de rastreio preconizados na prática clínica, tendo consequências negativas e irreversíveis. Sabe-se que o rastreio é recomendado mas ainda não há diretrizes muito claras e eficazes. O diagnóstico atempado é extremamente importante para reduzir as consequências. Com este estudo pretendem-se avaliar a prevalência de neuropatia motora e analisar o possível benefício da utilização da eletromiografia na deteção precoce de neuropatia motora periférica, numa fase subclínica da doença. Pretendemos também classificar melhor possíveis fatores de risco para o desenvolvimento desta patologia tornando-nos mais aptos e com mais conhecimento para no futuro criar métodos de rastreio mais eficazes e eficientes, melhorando a nossa

PARTICIPANTES PREVISTOS PARA A INVESTIGAÇÃO

Estão definidos critérios de inclusão / de exclusão de doentes? ☐ Não ☒ Sim

Onde e como serão recrutados os participantes no estudo?

Pedido de colaboração em consulta de Endocrino e Doenças Metabólicas de Pediatria do CUHSJ

Qual é o tamanho amostral? 50

Está prevista a recolha de material biológico específico para a investigação?

☒ Não ☐ Sim. Identifique e justifique:

BENEFÍCIO/RISCO DECORRENTE DA PARTICIPAÇÃO

Descreva os benefícios previsíveis:

Deteção precoce de neuropatia motora periférica numa fase subclínica diminuindo as suas consequências negativas

Descreva os riscos/incómodos previsíveis:

Transtorno relacionado com a perda de tempo de vida pessoal na realização da eletromiografia.

Também o envolvimento psicológico durante a realização do exame e devido ao possível diagnóstico precoce de

CONSENTIMENTO INFORMADO, ESCLARECIDO E LIVRE

Prevê a obtenção de consentimento informado? ☒ Sim ☐ Não

Se não, justifique: _____

Prevê informação escrita para os participantes? ☒ Sim. **Enviar modelo preenchido.**

☐ Não. Justifique: _____

O modelo para obtenção de consentimento é o modelo institucional do CHUSJ? ☒ Sim ☐ Não

PROTEÇÃO DE DADOS PESSOAIS

Necessita consultar registos clínicos? ☐ Não ☒ Sim

Está previsto o tratamento de dados pessoais? ☐ Não ☒ Sim

Se sim, de que forma é garantida a pseudonimização dos dados recolhidos? (codificação, uso de filtros, siglas...)

A pseudonimização será garantida através da substituição de informações identificáveis por identificadores únicos, como códigos alfanuméricos, de modo que os dados não possam ser facilmente relacionados a indivíduos específicos sem informações adicionais.

Descreva o património informacional a que pretende ter acesso (v.g.: nome, idade, data nascimento, idade, morada, diagnóstico, história clínica, tratamento...):

Pretendo ter acesso a dados demográficos (idade, sexo), duração DMT1, medicação, peso, altura, circunferência da cintura, resultados de análises (HbA1c, glicose, HDL, LDL, triglicerídeos, vitamina D, função renal, análise sumária da urina), TIR (Time In Range) e Coeficiente de variabilidade e Glicose média. Exame físico e neurológico (Pesquisar atrofia muscular e presença de úlceras, Reflexo tendão Aquiles, Sensação vibratória (diapasão), Sensação dolorosa (pin), Temperatura, Sensibilidade cutânea- Monofilamento semmes- Weinstein, Força muscular (Flexão e extensão (0-5) tornozelo, joelho)) Avaliação de sintomas (Ardor/ queimadura, Choques, picadelas, dor

Está prevista a criação de um Banco de Dados? ☐ Não ☒ Sim

Está previsto o registo de som ou de imagem dos participantes? ☒ Não ☐ Sim

O estudo envolve investigação genética? ☒ Não ☐ Sim

PROPRIEDADE INTELECTUAL

De quem será a propriedade intelectual da investigação e seus resultados?

☒ Investigador ☐ Promotor ☐ Serviço/CHUSJ ☐ Todos

DIVULGAÇÃO DOS RESULTADOS

Está prevista a divulgação dos resultados da investigação? ☐ Não ☒ Sim

Se sim, estão definidos critérios de publicação? ☒ Não ☐ Sim. Quais? _____

CONTRAPARTIDAS PARA OS PARTICIPANTES

Estão previstas contrapartidas para os participantes? ☒ Não ☐ Sim

Pela participação? ☒ Não ☐ Sim

Pelas deslocações? ☒ Não ☐ Sim

Pelas perdas salariais? ☒ Não ☐ Sim

Por outras perdas e/ou danos? ☒ Não ☐ Sim

EXAMES COMPLEMENTARES DE DIAGNÓSTICO

Estão previstos exames complementares de diagnóstico, para além dos inerentes à rotina assistencial?

☐ Não ☒ Sim. Quais? Eletromiografia

Por quem serão suportados estes custos?

CHUSJ

PROTOCOLO FINANCEIRO

Existe protocolo financeiro com o CHUSJ? ☒ Não ☐ Sim

SEGURO

Este estudo prevê intervenção clínica que implique a existência de um seguro para os participantes?

☒ Não ☐ Sim (se sim, junte cópia da respetiva Apólice)

Data previsível para fim do acesso aos dados: 31 / 1 / 25

DOCUMENTOS ANEXOS (em suporte digital)

- ☒ Pedido de autorização ao Presidente do Conselho de Administração do CHUSJ
- ☒ Protocolo do estudo
- ☐ Caderno de recolha de dados (CRF)
- ☒ Declaração Diretor(es) Serviço(s)
- ☒ Informação Orientador
- ☐ Profissional de ligação
- ☒ Informação aos participantes
- ☒ Modelo de consentimento a utilizar
- ☐ Instrumentos de avaliação (escalas, inquéritos) _____
- ☒ Curriculum/a vitae (investigador/es)
- ☐ Questionário para Encarregado de Proteção de Dados (EPD)
- ☒ Termo de Responsabilidade do Centro Académico Clínico (para investigadores da FMUP que não pertençam ao CHUSJ)
- ☐ Protocolo financeiro
- ☐ Outros: _____

TERMO DE RESPONSABILIDADE

Aceitação dos termos e condições de reutilização

Cumulativamente com as obrigações decorrentes da *Lei n.º 26/2016, de 22 de agosto*, maxime dos *n.º 2 e 3 do artigo 21* e o *n.º 1 e 2 do artigo 12*, ao submeter o presente pedido, concordo e fico ainda juridicamente vinculado aos seguintes termos e condições:

- Comprometo-me a manter confidencial toda a informação à qual vou ter acesso;
- Após explicação do RAI do CHUSJ, embora a Lei 26/2016, de 22 de agosto, imponha como requisito a anonimização sem possibilidades de reversão, tal desiderato, é não só uma impossibilidade matemática já comprovada, como ainda resulta num prejuízo para a investigação, face à quantidade e à qualidade da informação a retirar à fonte, razão pela qual, concordando com o RAI, assumimos como compromisso a pseudonimização, o que impõe uma avaliação e gestão do risco, num quadro ético-jurídico que aceitamos e nos comprometemos a colaborar e respeitar;
- Não vou elaborar registos, suscetíveis de identificar ou tornar identificável a identidade das pessoas a quem os mesmos dizem respeito;
- Comprometo-me a consultar os processos clínicos nos termos e locais que me forem indicados para o efeito;
- Tomei conhecimento, que a violação de qualquer dos compromissos aqui assumidos, poderá resultar no apuramento de responsabilidades disciplinares, civis e penais, e ainda, à impossibilidade futura de aceder a informação de saúde para fins de investigação.
- Independentemente de requerer a Certidão de Reutilização, DAta REuse Certificate for Research (DARE), comprometo-me a citar as fontes, sempre que publicitar, no todo ou em parte, resultados da presente investigação.

COMPROMISSO DE HONRA E DECLARAÇÃO DE INTERESSES

Eu, Joana Helena de Bourbon Faria Ribeiro Lopes,

abaixo assinado, na qualidade de Investigador Principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes na Declaração de Helsínquia (1960, e sucessivas emendas), da Organização Mundial de Saúde, da Convenção de Oviedo e das 'Boas Práticas Clínicas' (GCP/ICH) no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CE de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo, nos últimos três meses. Comprometo-me a entregar à CE o relatório final da investigação, assim que concluído.

Assinado por: **JOANA HELENA DE BOURBON FARIA RIBEIRO LOPES**
Num. de Identificação: 14731777
Data: 2024.02.24 18:47:27+00'00'



CARTÃO DE CIDADÃO

Data: 24 / 02 / 2024

assinatura

COMISSÃO DE ÉTICA CHUSJ/FMUP

Parecer da CE, emitido na reunião plenária de 22 / 03 / 2024

. Centro Hospitalar **São João**.

Aguarda esclarecimentos.

CONSIDERADOS QUE FORAM COMO SATISFATÓRIOS OS ESCLARECIMENTOS PRESTADOS PELO(A) INVESTIGADOR(A), A CES APROVA POR UNANIMIDADE O PARECER DO RELATOR, PELO QUE NADA TEM A OPOR À REALIZAÇÃO DESTE PROJETO DE INVESTIGAÇÃO.

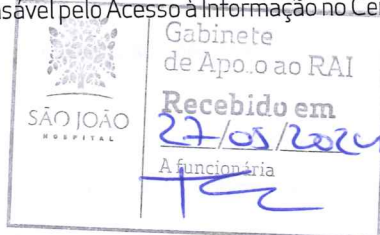
. Centro Hosp. Univ. São João.
Comissão de Ética
Manuel Vaz Silva
Presidente

. Centro Hosp. Univ. São João.
Comissão de Ética
Manuel Vaz Silva
Presidente

24.05.2024

RAI 24011220

RAI - Responsável pelo Acesso à Informação no Centro Hospitalar Universitário de São João (Art. 9º, Lei 26/2016 de 22 de Agosto)



AUTORIZADO
RAI - Responsável pelo Acesso à Informação no Centro Hospitalar de São João
(Art. 9º, Lei 26/2016, de 22/8)

24.5.2024

CENTRO DE EPIDEMIOLOGIA HOSPITALAR



ENCARREGADO DE PROTEÇÃO DE DADOS (EPD) UNIDADE LOCAL DE SAÚDE SÃO JOÃO, E.P.E.

Paulo Alexandre Mota da Silva

Encarregado de Proteção de Dados da ULS SÃO JOÃO

epd@ulssjoao.min-saude.pt

Ref.º CES ULSSJ: 104 / 2024

Título do Projeto Rastreio de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1.

Responsável pelo tratamento Jacinta Rodrigues Fonseca

Instituição Joana Helena Bourbon Faria Ribeiro Lopes

Unidade Local de Saúde de São João (ULS SÃO JOÃO)

Faculdade de Medicina da Universidade do Porto (FMUP)

Investigador Interno Externo

Contacto telefónico 914314972

Endereço Electrónico u013212@ulssjoao.min-saude.pt

Profissional de Ligação Não aplicável

Amostra 50

Análise de Risco Tolerável Baixo Elevado Muito Elevado

Parecer do EPD:

Data: 19/07/2024

Finalidade: Avaliação da prevalência de neuropatia motora em crianças e adolescentes com Diabetes Mellitus tipo 1. Avaliar se há uma associação entre os resultados da eletromiografia e parâmetros clínicos e bioquímicos de cada criança ou adolescente que podem aumentar o risco de neuropatia diabética periférica motora.

Licitude: fundamento previsto no artigo 6(1)(a) e 9(2)(a) do RGPD.

Categorias de dados pessoais: variáveis identificadas com detalhe na AIPD, datada de 29/05/2024, ponto 13, tendo presente o princípio da minimização dos dados.

Conservação: os dados serão alvo de pseudonimização, armazenados em local seguro, em área restrita com acesso limitado ao Investigador Principal, com acesso a ficheiros protegido por palavra-passe, efetuando-se a conservação até a conclusão da investigação, durante o prazo máximo de quatorze (14) meses. Os dados recolhidos serão destruídos após a finalização do estudo.

Comunicação de Dados: há partilha de dados pessoais (pseudonimizados).

Conclusão: Face ao exposto, e observadas as recomendações, entende-se que o presente projeto está em conformidade com o RGPD pelo que sou de parecer favorável quanto à sua realização.

Recomendações:

- Sempre que o consentimento do titular for o fundamento de legitimidade adequado para o tratamento de dados, dever-se-á assegurar que o mesmo é válido nas condições legalmente exigíveis: uma manifestação de vontade livre, específica, informada e inequívoca. Neste contexto, o consentimento deverá ser objeto de reflexão por parte do participante fora do ambiente hospitalar, devendo para tal, existir a possibilidade de o mesmo remeter o consentimento por correio em envelope RSF;
- Reforçar as medidas de segurança previstas para a conservação dos documentos em formato de papel que impeçam o acesso à informação a pessoas não autorizadas, bem como o seu manuseamento indevido;
- Garantir medidas de segurança adicionais no transporte dos dados com recurso a dispositivos electrónicos de armazenamento (Laptop, Pen, E-mail / Cloud Institucional), nomeadamente através de medidas de cifragem e autenticação; Garantir medidas de segurança adicionais (ex. transformar os dados com recursos a técnicas de generalização, perturbação e/ou como último recurso, a supressão de dados) para os dados que, ainda que pseudonimizados, contém elementos informativos
- que no seu conjunto possibilitam a re-identificação dos participantes, tendo presente a amostra em estudo (crianças e adolescentes seguidas nas consultas de endocrinologia e doenças metabólicas da área de Pediatria), em particular na fase de disseminação ou publicação dos resultados (incluindo repositórios científicos).
- A chave de descodificação que permite a re-identificação dos titulares dos dados (participantes) deve ficar sempre na posse do Elo de Ligação ULS SÃO JOÃO e protegida de acessos indevidos / terceiros;
- Em caso de necessidade de extensão de prazo e/ou de qualquer alteração dos pressupostos atinentes ao presente parecer o Investigador Principal deverá solicitar a reapreciação do projeto de investigação junto do EPD.

Revisão AIPD:



Data da próxima revisão: __/__/__



Não carece de revisão.

Anexos:

1. Processo CES n.º 104/2024
2. Parecer CES (24/05/2024)
3. AIPD (29/05/2024)
4. Consentimento Informado e Informação ao Participante
5. Protocolo de Investigação

Encarregado de Proteção de Dados

Assinado por: **PAULO ALEXANDRE MOTA DA SILVA**

Data: 2024.07.22 10:45:30+01'00'

Localização: ULS SÃO JOÃO



CARTÃO DE CIDADÃO





SÃO JOÃO

PARA INVESTIGAÇÃO CLÍNICA

Considerando a "Declaração de Helsínquia" da Associação Médica Mundial (Helsínquia 1964; Tóquio 1975; Veneza 1983; Hong Kong 1989; Somerset West 1996, Edimburgo 2000, Seoul 2008, Fortaleza 2013)

Designação do Estudo (datilografado em português)

Este estudo denominado "rastreamento de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1" tem como objetivo avaliar uma consequência de diabetes tipo 1 que afeta os nervos e músculos. Através da realização de um exame, eletromiografia, queremos avaliar quantas pessoas contêm esta consequência bem como fatores que podem aumentar a probabilidade de a ter. E, por isso, iremos também relacionar dados clínicos de cada participante com os resultados do exame.

Confirmando que expliquei ao participante/representante legal, de forma adequada e compreensível, a investigação referida, os benefícios, os riscos e possíveis complicações associadas à sua realização.

Informação escrita em anexo: ☐ Não ☒ Sim (Nº de páginas 2)

O investigador responsável

Nome: Jacinta Rodrigues Fonseca

datilografado

Data: 21 / 05 / 2024

assinatura

Identificação do participante

Nome: _____

datilografado

BI/CC nº: _____

Participante/ Representante legal

- Compreendi a explicação que me foi facultada acerca do estudo que se tenciona realizar: os objetivos, os métodos, os benefícios previstos, os riscos potenciais, eventual desconforto e política de acesso a registos clínicos.
- Solicitei todas as informações de que necessitei, sabendo que o esclarecimento é fundamental para uma boa decisão.
- Fui informado da possibilidade de livremente recusar ou abandonar a todo o tempo a participação no estudo, sem que isso possa ter como efeito qualquer prejuízo na assistência que me é prestada.
- Declaro não ter sido incluído em nenhum outro projeto de investigação nos últimos três meses.
- Concorde com a participação neste estudo, de acordo com os esclarecimentos que me foram prestados, como consta neste documento, do qual me foi entregue uma cópia.

Data: ____ / ____ / ____

assinatura

Nome (Pais/Representante legal, se aplicável): _____

BI/CC nº: _____

Grau de parentesco: _____

datilografado

Data: ____ / ____ / ____

assinatura



SÃO JOÃO

PARA INVESTIGAÇÃO CLÍNICA

Considerando a "Declaração de Helsínquia" da Associação Médica Mundial (Helsínquia 1964; Tóquio 1975; Veneza 1983; Hong Kong 1989; Somerset West 1996; Edimburgo 2000; Seoul 2008; Fortaleza 2013)

Designação do Estudo *(datilografado em português)*

O título do estudo denomina-se rastreio de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1. Queremos avaliar a prevalência de neuropatia motora através da realização de uma eletromiografia. À posteriori, temos como objetivo secundário, correlacionar dados clínicos e bioquímicos de cada participante com os resultados da eletromiografia para detetar possíveis associações e fatores de risco para o desenvolvimento desta patologia.

Confirmo que expliquei ao participante/representante legal, de forma adequada e compreensível, a investigação referida, os benefícios, os riscos e possíveis complicações associadas à sua realização.

Informação escrita em anexo: ☐ Não ☒ Sim (Nº de páginas 2)

O investigador responsável

Nome: Jacinta Rodrigues Fonseca
datilografado

Data: 3 / 5 / 2024

Jacinta Fonseca
assinatura

Identificação do participante

Nome: _____
datilografado

BI/ CC nº: _____

Participante/ Representante legal

- Compreendi a explicação que me foi facultada acerca do estudo que se tenciona realizar: os objetivos, os métodos, os benefícios previstos, os riscos potenciais, eventual desconforto e política de acesso a registos clínicos.
- Solicitei todas as informações de que necessitei, sabendo que o esclarecimento é fundamental para uma boa decisão.
- Fui informado da possibilidade de livremente recusar ou abandonar a todo o tempo a participação no estudo, sem que isso possa ter como efeito qualquer prejuízo na assistência que me é prestada.
- Declaro não ter sido incluído em nenhum outro projeto de investigação nos últimos três meses.
- Concordo com a participação neste estudo, de acordo com os esclarecimentos que me foram prestados, como consta neste documento, do qual me foi entregue uma cópia.

Data: ____ / ____ / ____

assinatura

Nome (Pais/Representante legal, se aplicável): _____

BI/ CC nº: _____

Grau de parentesco: _____

datilografado

Data: ____ / ____ / ____

assinatura

INFORMAÇÃO AO PARTICIPANTE NA INVESTIGAÇÃO

(Crianças 12-15 anos)

Caro(a) Participante,

Gostaríamos de convidá-lo(a) a participar num estudo de pesquisa clínica denominado "rastreamento de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1" que tem como objetivo avaliar uma consequência de diabetes tipo 1 que afeta os nervos e músculos. Através da realização de um exame, eletromiografia, queremos avaliar quantas pessoas têm esta consequência bem como fatores que podem aumentar a probabilidade de a ter. E, por isso, iremos também relacionar dados clínicos de cada participante com os resultados do exame.

Título do Estudo: Rastreamento de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1

Investigador Principal: Jacinta Rodrigues Fonseca

Contacto: 914314972 / u013212@ulssjoao.min-saude.pt

Co investigadoras:

Contacto: Joana Bourbon Lopes- 926668035/ up201908122@up.pt

Contacto: Dra. Cíntia Correia- 910006244 / u013212@ulssjoao.min-saude.pt

Caso tenhas dúvidas sobre a forma como os seus dados pessoais são tratados, para saber mais sobre os seus direitos no âmbito da proteção de dados, pode entrar em contacto com o Encarregado de Proteção de Dados da ULS SÃO JOÃO através do endereço de email: epd@ulssjoao.min-saude.pt

Os participantes irão realizar uma eletromiografia, que é uma técnica de avaliação da atividade elétrica que permite identificar doenças dos nervos e músculos.

Os benefícios esperados incluem a deteção da doença motora numa fase inicial, diminuindo as suas consequências negativas e permitindo identificação de possíveis fatores de risco. Isto levará a um ganho de conhecimento nesta área e poderá melhorar os métodos de tratamento.

Reconhecendo os incómodos derivados da participação tempo e stress, apelamos ao esforço solidário numa causa de interesse próprio e comum.

A participação neste estudo é voluntária e a qualquer momento podes desistir ou abandonar, sendo essa vontade sempre respeitada.

Terás tempo suficiente para refletir sobre o pedido de participação, inclusive ouvindo a opinião de familiares e/ou amigos podendo ser, posteriormente, remetido por correio em envelope RSF.

Tens liberdade para decidir se deseja participar ou não, sem qualquer tipo de julgamento.

Tens o direito de retirar o consentimento dado a qualquer momento, sem que isso comprometa o relacionamento com o médico ou o respeito pelos direitos à assistência que te é devida.

Caso considere que os seus dados não estão a ser objeto de tratamento legítimo, pode, a todo o momento, apresentar uma reclamação junto da autoridade competente, a Comissão Nacional de Proteção de Dados (www.cnpd.pt).

A privacidade e a confidencialidade serão garantidas durante todo o estudo. Os dados serão conservados por um período específico de 14 meses.

Este estudo foi aprovado pela Comissão de Ética do Centro Hospitalar Universitário do São João.

Por favor, sente-te à vontade para entrar em contato connosco se tiver alguma dúvida ou precisar de mais informações sobre o estudo. A tua participação é extremamente valiosa e apreciada.

Atenciosamente,

Participante

INFORMAÇÃO AO PARTICIPANTE NA INVESTIGAÇÃO

Caro(a) Participante,

Gostaríamos de convidá-lo(a) a participar num estudo de pesquisa clínica denominado "rastreo de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1" que tem como objetivo avaliar uma consequência de diabetes tipo 1 que afeta os nervos e músculos. Através da realização de um exame, eletromiografia, queremos avaliar quantas pessoas contêm esta consequência bem como fatores que podem aumentar a probabilidade de a ter. E, por isso, iremos também relacionar dados clínicos de cada participante com os resultados do exame.

Título do Estudo: Rastreo de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1

Investigador Principal: Jacinta Rodrigues Fonseca

Contacto: 914314972 / u013212@ulssjoao.min-saude.pt

Co investigadoras:

Contacto: Joana Bourbon Lopes- 926668035/ up201908122@up.pt

Contacto: Dra. Cíntia Correia- 910006244 / u013212@ulssjoao.min-saude.pt

Caso tenha dúvidas sobre a forma como os seus dados pessoais são tratados, para saber mais sobre os seus direitos no âmbito da proteção de dados, pode entrar em contacto com o Encarregado de Proteção de Dados da ULS SÃO JOÃO através do endereço de email: epd@ulssjoao.min-saude.pt

Os participantes irão realizar uma eletromiografia, que é uma técnica de avaliação da atividade elétrica que permite identificar patologias dos músculos tanto da placa neuromuscular como dos nervos.

Os benefícios esperados incluem a deteção precoce de neuropatia motora numa fase subclínica, diminuindo as suas consequências negativas e a identificação de possíveis fatores de risco, contribuindo para um ganho de conhecimento nesta área que vai ajudar a melhorar os métodos de rastreio.

Os incómodos derivados da participação podem incluir dificuldade relacionada com a perda de tempo pessoal para a realização da eletromiografia, stresse psicológico associado ao exame e a possível identificação de neuropatia motora como resultado de diabetes mellitus tipo 1.

A participação neste estudo é voluntária e a qualquer momento pode desistir ou abandonar, sendo essa vontade sempre respeitada.

Terá tempo suficiente para refletir sobre o pedido de participação, inclusive ouvindo a opinião de familiares e/ou amigos, podendo ser, posteriormente, remetido por correio em envelope RSF.

Tem liberdade para decidir se deseja participar ou não, sem qualquer tipo de julgamento.

Tem o direito de retirar o consentimento dado a qualquer momento, sem que isso comprometa o relacionamento com o médico ou o respeito pelos direitos à assistência que lhe é devida.

Caso considere que os seus dados não estão a ser objeto de tratamento legítimo, pode, a todo o momento, apresentar uma reclamação junto da autoridade competente, a Comissão Nacional de Proteção de Dados (www.cnpd.pt).

A privacidade e a confidencialidade serão garantidas durante todo o estudo. Os dados serão conservados por um período específico de 14 meses.

Este estudo foi aprovado pela Comissão de Ética do Centro Hospitalar Universitário do São João.

Por favor, sente-te à vontade para entrar em contato connosco se tiver alguma dúvida ou precisar de mais informações sobre o estudo. A tua participação é extremamente valiosa e apreciada.

Atenciosamente,

Participante



CUIDADOS
DE SAÚDE PRIMÁRIOS

Título do Projeto: Rastreio de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo

Onde decorre o Estudo: No Serviço de Pediatria Médica do CHUSJ.

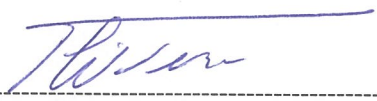
Objetivos do Estudo:

Este projeto tem como objetivo primário avaliar a prevalência de neuropatia motora em crianças e adolescentes com Diabetes Mellitus tipo 1. Será realizado uma eletromiografia em crianças e ou adolescentes com mais de 10 de idade, diagnosticadas há mais de 5 anos e que realizam tratamento com bomba infusora de insulina com intuito de realizar uma caracterização eletrofisiológica e identificar possíveis padrões de envolvimento motor. Á posteriori irá ser analisado se há uma associação entre os resultados da eletromiografia e alguns parâmetros clínicos e bioquímicos das crianças que, poderão ou não aumentar o risco de neuropatia diabética motora. Estudo realizado no âmbito do Mestrado Integrado em Medicina da FMUP, sob orientação da Prof.^a Doutora Cíntia Gonçalves de Castro Correia.

Trata-se de um estudo cross-sectional com um tamanho da amostra estimado de 50 doentes, com mais de 10 anos de idade e mais de 5 anos de evolução da doença e seguidos na Consulta de Endócrino e Doenças Metabólicas de Pediatria do CHUSJ.

Dado conhecimento do estudo à Unidade de Neurofisiologia - Dr.Fernando Silveira, responsável pela realização dos estudos de condução nervosa (ECN) e eletromiografias (EMGs).

Porto, 8 de abril de 2024



Fernando Silveira
Assistente técnico de
Neurofisiologia

Realização de Investigação



SÃO JOÃO

Exmo(a). Senhor(a) Diretor(a) do Serviço de Pediatria

Nome do Investigador Principal:

Jacinta Rodrigues Fonseca

Título da Investigação:

Rastreio de Neuropatia Motora em Crianças ou Adolescentes com Diabetes Mellitus tipo 1.

Pretendendo realizar a investigação em epígrafe no Centro Hospitalar Universitário de São João, solicito a V. Exa., na qualidade de Investigador, a emissão de declaração abaixo indicada.

Com os melhores cumprimentos.

O Investigador

Porto, 3 de Maio de 2024.

Jacinta Fonseca
assinatura

Para ser presente à Comissão de Ética do Centro Hospitalar Universitário de São João, declaro que o Serviço de Pediatria reúne as condições logísticas e de recursos humanos que permitem a realização da investigação em apreço.

Porto, 20 de Maio de 2024.

O(A) Diretor(a) de Serviço

Emília Almeida
assinatura