PAINFUL DIABETIC PERIPHERAL NEUROPATHY AND SCS: USING THE PRODUCT SURVEILLANCE REGISTRY (PSR) TO COLLECT EVIDENCE

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INTRODUCTION

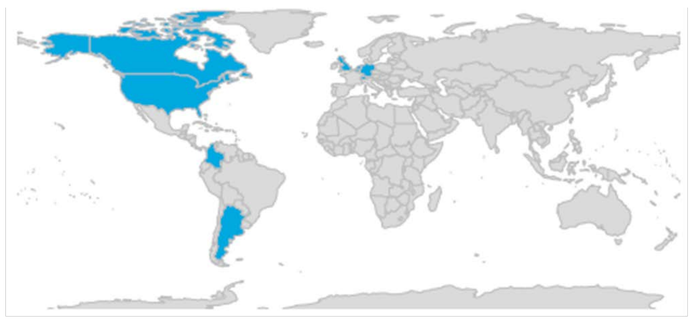
Painful Diabetic Peripheral Neuropathy (DPN) is a common complication of diabetes that often results in a typical 'glove and stocking' pain distribution. Patients can experience a variety of symptoms, including prickling or tingling, burning, shooting or stabbing pain or unusual sensations, which can interfere with sleep and quality of Life (QoL) leading to reduced activity levels, depression and social isolation[1].

Traditional Spinal Cord Stimulation (SCS) is an evidence-based treatment for lower limb DPN, with demonstrated significant impacts on pain relief and in QoL[2,3,4]. New stimulation paradigms may offer additional options for PDN patients.

This study aims to collect data on pain, QoL, stimulation paradigms, sleep and activity.

Figure 1 – Medtronic PSR

6228	1634	10	52,463
SCS Patients ever enrolled in the registry	SCS Patients active in the registry	Countries contributing to the SCS registry	Years of SCS device experience in the registry



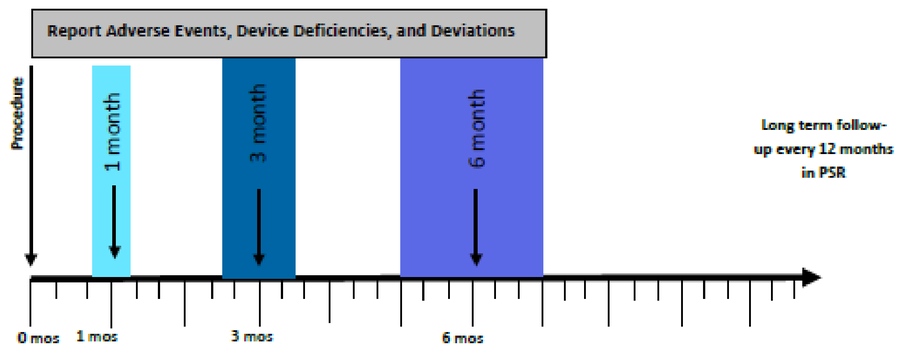
METHODS

A sub-study within the Medtronic Product Surveillance Registry (PSR; Figure 1) is being conducted to evaluate real world data on the effects of SCS on pain, QoL (including sleep quality and quantity and activity level), for subjects enrolled and receiving SCS for the treatment of DPN.

The use of different SCS stimulation paradigms e.g. Differential Targeted Multiplexed™ (also known as DTM™), conventional, or High Density (HD) SCS is being evaluated. Eligible Patients for a SCS system for the treatment of DPN will be enrolled in this study. Subject eligibility includes having pain for more than 12 months that is refractory to the standard of care/conventional medical management, with a minimum pain intensity of ≥5 measured on the NRS. Patients with pain in their upper limbs and/or a Hemoglobin A1c >10 will be excluded.

Patients in the cohort will be followed for up to 6 -months after implant, with data collected at 1-month, 3-month and 6-month follow-up visits. Visits will be performed according to the routine clinical care practices of the hospital. After the 6-month follow-up, patients will be maintained in the PSR and followed-up annually (Figure 2). Outcomes to be assessed at follow-up visits include pain intensity, quality of life, sleep and activity.

Figure 1 – Study design timeline



RESULTS

This study is currently recruiting study subjects from five sites in Europe and will report on the objectives to describe the number of patients with positive trial stimulation, different stimulation paradigms in painful DPN patients and the effect of the different stimulation methodology on pain. In addition, sleep and the effect of SCS on activity level will be evaluated.

CONCLUSIONS

The study will provide evidence to support the evolution and flexibility of new stimulation paradigms such as DTM™ in the SCS space for DPN. The study will also provide additional data on the effects of SCS for improving sleep and activity level.

References

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Disclosure

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