Spinal Cord stimulation for Intractable MONOneuropathy

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Assessing the effects of SCS in patients with mononeuropathy measured according to the IMMPACT guidelines (pain reduction, improvement of quality of life, physical and emotional functioning, medication use, adverse events), and assessing the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON56537

Source
ToetsingOnline

Brief title
SCIMONO

Condition

- Peripheral neuropathies

Synonym
mononeuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Boston Scientific,Boston Scientific Cooperation International

Intervention

Keyword: Mononeuropathy, Peripheral neuropathic pain, Spinal Cord Stimulation

Outcome measures

Primary outcome

The effect of 6 months of spinal cord stimulation in the test subjects on the 'IMMPACT guidelines' (perceived pain intensity, quality of life, physical and emotional functioning, and medication use)

Secondary outcome

- Effect of individually optimized spinal cord stimulation settings

- Effect of 3 or 6 months of spinal cord stimulation on thermographic images, immunology, QST, and EMG.

- Personal preference for spinal cord stimulation settings of the test subjects

Study description

Background summary

Peripheral neuropathic pain has a high incidence and prevalence. Damage to a peripheral nerve has all kinds of causes, for example post-traumatic, postsurgical, pressure neuropathy, etc. If the pain is in a single nerve, this is called a mononeuropathy; If it is located in a broader area and involves several nerves, we call it a polyneuropathy. The pain can be moderate to severe and significantly impact functionality and quality of life. The regular treatment of neuropathy is not harmful and highly variable, and the effect of the treatment is often disappointing. The condition is associated with high direct and indirect costs.

Several randomized controlled trials have shown that spinal cord stimulation is an effective treatment for patients with (diabetic) polyneuropathy. For mononeuropathy, there have been no randomized controlled trials to assess effectiveness, but there have been a number of case series that positively assessed spinal cord stimulation for mononeuropathy.

Study objective

Assessing the effects of SCS in patients with mononeuropathy measured according to the IMMPACT guidelines (pain reduction, improvement of quality of life, physical and emotional functioning, medication use, adverse events), and assessing the stimulation paradigm preferences in these patients.

Study design

It is a mono-center exploratory pilot study with at least 12 patients with peripheral mononeuropathic pain who receive a spinal cord stimulator at Erasmus MC.

Intervention

Spinal cord stimulator implantation and 3 times blood collection

Study burden and risks

Burden: at least 8 appointments and examinations per subject. Subject must keep a pain diary for 6 months. Recovery after spinal cord stimulation implantation can also be painful.
Risk: risk that spinal cord stimulation does not (sufficiently) reduce pain. Negligible risk of the measurements. Risk of infection or complication after spinal cord stimulation implantation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Suffering from painful peripheral mononeuropathy in the distal extremities, preferably post-traumatic or post-surgical, confirmed by EMG
- Symptoms refractory to conventional medical management for at least 6 months according to treating physician
- 18 years or older
- At least 5 out of 10 on the numerical rating scale for pain (average pain intensity in week prior to assessment)

Exclusion criteria

- Mononeuropathy located in the head or torso
- Mononeuropathy by avulsion at the plexus brachialis
- Life expectancy <1 year

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2024
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Spinal Cord Stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-02-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-03-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85325.078.23