A Post-market Study Evaluating the Prodigy Neuromodulation System for the Management of Failed Back Surgery Syndrome or Chronic Intractable Pain of the Trunk and/or limbs

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The primary objective of this study is to confirm the long term efficacy of the ProdigyTM neuromodulation system in the management of failed back surgery syndrome or chronic intractable pain of the trunk and/or limbs.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40764

Source
ToetsingOnline

Brief title
Prodigy-I study

Condition

- Other condition

Synonym
Chronic pain, failed back surgery syndrome

Health condition

Chronische pijn waarvoor geen alternatieve behandeling meer is

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: burst therapy, chronic pain, Failed Back Surgery Syndrome, Neuromodulation

Outcome measures

Primary outcome

The primary endpoint is the percentage of pain relief at the 3-month visit

compared to baseline visit, as measured by the Visual Analog Scale (VAS).

Secondary outcome

• Pain relief at the 3-month visit compared to EMPOWER Perc post market study

(tonic stimulation)

• Paresthesia mapping at the 3-month visit. This endpoint will also be compared

to paresthesia mapping results from the EMPOWER Perc post market study (tonic

stimulation).

• Pain relief at the 12-month visit compared to baseline visit, as measured by

VAS

• Improvement of patient pain catastrophizing at the 12-month visit compared to

baseline visit, as measured by the Pain Catastrophizing Scale (PCS)

• Reduction of use of analgesics at the 12-month visit compared to baseline

visit

• Improvement of the quality of life at the 12-month visit compared to baseline

visit, as measured by the European Questionnaire-5 Dimensions

• Rate of serious adverse events (SAEs) and/or procedure/device-related adverse

events ((S)ADEs)

Study description

Background summary

Spinal cord stimulation (SCS) is a minimally invasive and reversible procedure in which electrical leads are placed in the epidural space, applying stimulation to the dorsal column. SCS has been used successfully to treat a variety of pain conditions including, diabetic neuropathy3, failed back surgery syndrome4,5,6,7, complex regional pain syndrome8,9, phantom limb pain10. SCS reduces pain, improves quality of life, reduces analgesic use, while having minimally significant adverse events
. The ProdigyTM system enables the use of both Tonic Stimulation and Burst Stimulation. The programming option currently available with approved neurostimulation devices, now referred to as Tonic Stimulation, is what patients are using today where the pulse is delivered at the same amplitude, frequency and pulse width and typically produces paresthesia (tingling sensation) over the patient*s area of pain.
Burst Stimulation is a subset of the existing stimulation Cycle mode where groups of pulses called bursts trains are repeated at a burst rate ; within each burst train, several pulses are issued at an intra-burst rate.
The amplitudes used for burst programming are reported to be significantly lower than those traditionally used for Tonic Stimulation which results in paresthesia free therapy with continued pain suppression.

This option provides clinicians with more programming options for their patients who wish to further individualize and optimize their neurostimulation treatment.

Study objective

The primary objective of this study is to confirm the long term efficacy of the ProdigyTM neuromodulation system in the management of failed back surgery syndrome or chronic intractable pain of the trunk and/or limbs.

Study design

International, multicenter, interventional, prospective and single-arm design

Intervention

Implantation of Prodigy Spinal Cord Stimulation System

Study burden and risks

Subjects will not be exposed to risks other than those associated with the risks of implantation of a SCS system.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

o Patient with chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and/or leg pain

o Patient is considered by the investigator as a candidate for implantation of a SCS system
o Patient is >= 18 years of age
o Patient must be willing and able to comply with study requirements
o Patient must indicate his/her understanding of the study and willingness to participate by signing an appropriate Informed Consent Form

Exclusion criteria

o Patient is immune-compromised
o Patient has history of cancer requiring active treatment in the last 6 months
o Patient has a documented history of substance abuse (narcotics, alcohol, etc.) or substance dependency in the last 6 months
o Patients with a SCS system or implantable infusion pump implanted previously
o Patient has a life expectancy of less than one year
o Patient is pregnant or is planning to become pregnant during the duration of the investigation
o Patient is unable to comply with the follow up schedule
o Patient needing legally authorized representative
o Patient unable to read and write
o Patient is currently participating in another clinical investigation with an active treatment arm

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2015
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	Neuromodulation Implantable Pacing Generator (IPG)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-12-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-01-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-01-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-08-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
ClinicalTrials.gov	NCT02143791
CCMO	NL48990.044.14