A randomized controlled trial to evaluate the efficacy of the Spinal Modulation Axium neurostimulator therapy as a treatment for persistent inguinal pain following surgical intervention.

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

Summary

ID

NL-OMON44602

Source
ToetsingOnline

Brief title
SMASHING

Condition

- Other condition
- Peripheral neuropathies

Synonym
chronic post surgical inguinal pain (CPIP), groin pain

Health condition

chronische liespijn

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Maxima Medisch Centrum Afdeling Chirurgie

Intervention

Keyword: Dorsal root ganglion, efficacy, Inguinal pain, Randomized

Outcome measures

Primary outcome

The percentage of subjects with *50% pain relief between the two groups and the

difference between groups in the change in numerical pain rating scale (NPRS).

Secondary outcome

* Repeat of primary objective measured at 12 months

* As Treated and Number Needed To Treat analysis of Axium

group and TNS failures combined at 6 months.

* Primary objective analysis as a true Intention to Treat using combined data

from the DRG group and TNS trial failures at 6 months

* Safety assessed by monitoring occurrence of device related (S)AEs

* Quality of life improvements and intergroup comparison between at 6 months

(EQ-5D)

* Physical functioning improvements and intergroup comparison at 6 months (BPI)

* Changes in Sensory Disturbances and intergroup comparison at 6 months

(Bedside Quantitative Sensory Testing, QST)

* Changes in Neuropathic Pain Scale (NPRS) and intergroup comparisons at 6

months

* Subject satisfaction and intergroup comparison at all follow up visits (7

point Likert Scale)

* Changes in healthcare resource utilisation and intergroup comparison at 6

months (Health Practitioner Visits/Medication Usage)

* Changes in sleep quality and intergroup comparison at 6 months (Daily Sleep

Interference Scale)

* All above mentioned secondary outcomes will be repeated at 12 months

follow-up for the treated group and will be compared to baseline.

Study description

Background summary

Initial clinical studies have shown that Spinal Cord Stimulation (SCS) of the Dorsal Root Ganglion (DRG) with the Spinal Modulation Axium® SCS system can significantly reduce chronic intractable pain in a variety of pain conditions. Successfully treated conditions include refractory, postoperative inguinal pain following various operative procedures such as mesh hernia repair, Pfannenstiel incision and femoral vein access. In the Netherlands it is not uncommon for patients suffering from chronic pain following such procedures to undergo a further surgery (neurectomy) to alleviate this pain. In clinical studies the neurectomy procedure has shown itself to be effective in approximately 70% of patients after one year. For those patients who are still in pain despite the neurectomy procedure the Axium® SCS system offers a further opportunity for patients to achieve pain relief and several such patients have been treated successfully with this therapy recently in the Netherlands. This Trial sets out to evaluate the efficacy of the Axium® SCS system as compared to conservative medical management (CMM) in subjects with persistent, chronic pain following open inguinal hernia repair or Pfannenstiel incision that had subsequently undergone and failed to respond to a neurectomy procedure.

Study objective

The primary objective of this Randomised Controlled Trial (RCT) is to evaluate the efficacy of DRG stimulation with the Axium® SCS system as compared to CMM

in terms of pain relief. Efficacy will be assessed by comparing the percentage of subjects with *50% pain relief between the two groups and the difference between groups in the change in numerical pain rating scale (NPRS). The trial is powered to demonstrate superiority of the Axium SCS System over CMM at the 6-month follow up visit.

Study design

This is a prospective, multicenter, randomized (1.2:1 * DRG:CMM) controlled trial (RCT) with optional crossover at 6 months designed to assess the efficacy of the Spinal Modulation Axium® SCS System for the treatment of intractable postsurgical pain in the Inguinal area, refractory to neurectomy.
Eligible subjects will be randomized to either DRG stimulation (Axium® SCS system) or CMM and prospectively followed for 12 months following; inclusion (CMM group) or implantation (Axium® group). Following data collection at the 6 month follow up visit subjects in the CMM group will be given the option to cross over to the alternate arm of the trial. Subsequently subjects will be followed prospectively for either a further 6 or 12 months dependent on the outcome of their procedure

Intervention

The commercially available Spinal Modulation Axium® SCS System for the management of chronic intractable pain (CE 567069).

Study burden and risks

There are no additional risks to the subjects participating in this trial. The implantation of the system is a standard procedure in the designated implantation centres, the device under Trial is being used within its approved (CE Mark) indication and regular follow up visits are standard practice for patients implanted with SCS devices such as and including the Axium® SCS system. Data that will be collected consists of questionnaires and keeping a diary seven days prior to follow-up visits concerned with; pain relief, quality of life, physical functioning and subject satisfaction. Some simple bedside sensory tests commonly utilised in pain management clinics will be done plus extensive quantitative sensory testing at baseline and final visit. These tests can be briefly uncomfortable and patients can refuse to undergo them without this having consequences for participation in the trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subject is at least 18 years old.
Subject is able and willing to comply with the follow-up schedule and protocol.
Chronic inguinal pain following pfannenstiel incision or inguinal hernia repair or laparoscopic inguinal repair for at least 6 months.
Previously undergone neurectomy procedure as a treatment for chronic inguinal pain.
Minimum baseline pain rating of 6 out of 10 in the inguinal area on an 11-point NPRS.
Subject is able to provide written informed consent.
Meets the inclusion criteria for the implantation of a neurostimulation system as set out by the Dutch Neuromodulation Society.
Subject has been screened by a multi-disciplanary panel including the designated psychologist of the Máxima Medical Centre Eindhoven and deemed suitable for implantation.
Neuropathic Pain as described by a score of *4 on the DN4 questionnaire

Exclusion criteria

Female subject of childbearing potential is pregnant/nursing or plans to become pregnant during the course of the trial.

Escalating or changing pain condition within the past month as evidenced by investigator examination.
Subject has had injection therapy or radiofrequency treatment of a target neural structure within the past 3 months
Subject currently has an active implantable device including ICD, pacemaker, spinal cord stimulator or intrathecal drug pump.
Subject is unable to operate the device.
Subject currently has an active infection.
Subject has participated in another clinical investigation within 30 days.
Subject has a coagulation disorder or uses anticoagulants that, in the opinion of the investigator, precludes participation.
Subject has a current or ongoing condition, which will probably require MRI investigation sometime in the following 2 years
Subject has had a spinal surgical procedure at or between vertebral levels T10-L2.
Subject had been diagnosed with cancer in the past 2 years, except for skin malignancies
Subject has a significant progressive peripheral or central neurological disorder such as Diabetic Polyneuropathy or Multiple Sclerosis

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2015
Enrollment:	78
Type:	Actual

Medical products/devices used

Generic name:	Axium® Spinal Cord Stimulation Systeem

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-11-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-03-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-09-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	29-12-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-01-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NCT02349659
CCMO	NL50024.015.14