Spinal Cord Stimulation for intractable chronic lower abdominal neuropathic pain caused by endometriosis

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The objective of this study is to assess the feasibility of SCS using the Wavewriter Alpha for control of treatment resistant endometriosis-related pain symptoms

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50815

Source
ToetsingOnline

Brief title
Spinal Cord Stimulation for Endometriosis pain

Condition

- Other condition

Synonym
chronic pain, endometriosis

Health condition

Chronische neuropathische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: Chronic pelvic pain, Endometriosis, Neuropathy, Spinal Cord Stimulation

Outcome measures

Primary outcome

Mean pain intensity and patients global impression of change at 6 months

Secondary outcome

• Mean pain: NRS pain score (3 times a day for 3 days) at baseline and 3-6 and 12 months post implant.

• The number (percentage) of subjects who achieve a reduction in the pain intensity of at least 50%(substantial change) or 30% (moderately important change) at 6 months compared to baseline.(12)

• Patient*s global impression of change(PGIC): dichotomous (better or improved versus not better or improved) at 3-6- and 12-months post implant.

• Change in quality of life: EHP 30 & SF36 at baseline and at 6- and 12-months post implant.

• Change in fatigue: EHP 30 at baseline and 6- and 12-months post implant

• Pain Catastrophizing assessed with the PCS at baseline, 6- and 12-months post implant.

• Central Sensitization Inventory at baseline and 6- and 12-months post implant.

• Pain medication use at baseline 3- 6- and 12-months post implant

• Lost working days: iPCQ Productivity Cost Questionnaire at baseline and at 6

months post implant

• Number of patients with a failed trial SCS

• Complications and side effects: 3, 6, and 12 months post implant.

Study description

Background summary

Endometriosis is a condition characterised by the presence and growth of ectopic endometrial tissue. Definitive diagnosis of endometriosis is by visualization and/or confirmed by histologic examination of excised lesions via laparoscopy. With a prevalence of 6-10%, endometriosis isn't rare. Besides complaints like dysmenorrhea, dyspareunia and infertility, a substantial percentage of these patients complain of chronic pelvic pain. This pain that should be seen as a form of centralised pain is notoriously hard to treat and results in a substantial loss in quality of life and impairment of professional and social functioning.
Spinal cord stimulation is a well accepted treatment for neuropathic pain. There is some evidence that patients with visceral pain can benefit from treatment with spinal cord stimulation. The question this study seeks to answer is wether spinal cord stimulation is a feasible treatment modality for patients suffering from chronic pelvic pain caused by endometriosis.

Study objective

The objective of this study is to assess the feasibility of SCS using the Wavewriter Alpha for control of treatment resistant endometriosis-related pain symptoms

Study design

This is a prospective, multicenter, unblinded feasibility study (pilot study) to assess the hypothesis that the chronic intractable severe pain from patients with endometriosis could be treated with SCS. Patients who failed all treatment options (hormonal, medical and surgical), and fulfil the inclusion criteria, and have signed the approved informed consent form will be enrolled in the study.
For this study 15 patients will receive an implant SCS. After implantation of the system the patients will be followed up for 1 year.
After the test period of 5 patients an interim analysis will be performed to assess if the study should continue, at least 2 patients should benefit from

the treatment with at least 50% pain relief for the study to continue.

Intervention

Implantation of a spinal cord stimulator with accompanying epidural leads (Boston Spectra Wavewriter System).

Study burden and risks

The risks patients are undergoing during implantation in this study are the same as the risks any patient faces undergoing neuromodulation. There is a very small risk of epidural hemorrhage (not higher than any form of regional anesthesia) and a risk of infection of the system. Routinely patients will receive pre operative prophylactic antibiotics and patients are made aware of the symptoms of the infection (pain, redness, fever, stiff neck).
Besides implantation of the neuromodulator the additional burden for the patients comprises of extra hospital visits.

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

- Patients with endometriosis/ adenomyosis confirmed at surgery and without options for further surgical treatment.
- Premenopausal woman aged >= 18 years
- Patients with at least one of the endometriosis related pain symptoms: dysmenorrhea, pelvic pain or dyspareunia.
- Mean pain NRS of at least 5 (scale 0-10).
- The pain complaints are therapy resistant (including hormonal, medical and/or surgical options)
- Refractory pain; Before neuromodulation patient has tried: Paracetamol, NSAIDs, Anti neuropathic pain therapy, TENS
- Neurologic exam without marked motor deficit.
- Meets all the inclusion criteria for the implantation of a neurostimulation system as typically utilized in the study center.
- Subject has been screened by a multi-disciplinary panel including a psychologist and deemed suitable for implantation
- Subject is able and willing to comply with the follow-up schedule and protocol
- Subject is able to provide written informed consent

Exclusion criteria

- Female subject of childbearing potential is pregnant/nursing or plans to become pregnant during the course of the study
- The presence of any malignancy
- BMI >=35
- Subject currently has an active implantable device including ICD, pacemaker, spinal cord stimulator or intrathecal drug pump
- Subject is unable to operate the device
- Previous Neurostimulation therapy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2022
Enrollment:	15
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	24-12-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL76287.018.21