Long Term Observational Study of the Safety and Efficacy of an Active Implantable Vagal Nerve Stimulation Device in Patients with Crohn*s Disease

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Primary Efficacy Objective The primary efficacy objective is to determine the long-term efficacy of NCAP (Neurostimulation of the Cholinergic Anti-inflammatory Pathway) delivered by the implanted device as assessed by the Crohn*s Disease Activity…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON47080

Source
ToetsingOnline

Brief title
SPM-010

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's Disease, Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: SetPoint Medical Corporation

Source(s) of monetary or material Support: SetPoint Medical Corporation

Intervention

Keyword: Crohn's disease, Medical Device, Nerve, Stimulation

Outcome measures

Primary outcome

Primary Endpoint:

Change from baseline in CDAI (Crohn*s Disease Activity Index)

Secondary outcome

Secondary Endpoints:

-Change from baseline in total score and sub-scale score for the IBDQ

(Inflammatory Bowel Disease Questionnaire)

-Change from baseline in total score and sub-scale score for the SHS (Short

Health Scale)

Study description

Background summary

Description of the Investigational Device
This study will utilize the Cyberonics VNS Systems that were implanted during study SPM-007. The devices are standard commercially available Cyberonics VNS System pulse generator and lead units, which were implanted in the same manner as is usually performed when the device is used for its currently labeled indications.

Rationale for Study
At the conclusion of study SPM-007 patients are given the option to either have the implanted device removed, to have the device remain in place but be permanently inactivated, or to continue to receive active treatments with the device by participating in the current study. This study will determine the long-term safety and efficacy of NCAP in patients with Crohn*s Disease who have participated in study SPM-007, using the Cyberonics devices implanted during

the SPM-007 study.

Study objective

Primary Efficacy Objective The primary efficacy objective is to determine the long-term efficacy of NCAP (Neurostimulation of the Cholinergic Anti-inflammatory Pathway) delivered by the implanted device as assessed by the Crohn*s Disease Activity Index (CDAI) score.

Study design

This will be an open label multicenter study of the safety and efficacy of an active implantable VNS device in patients with Crohn*s Disease. Patients who complete study SPM-007 will be enrolled in this study at the time of the last visit of the preceding study. The assessments at the last visit of the preceding study will also be used as baseline measures for the current study. If the patient has previously discontinued SPM-007 and greater than 30 days have elapsed since the final visit in SPM-007, baseline measures for the current study will be repeated, and an interim medical history will be taken to assess whether any new medical conditions were diagnosed in the time between studies. The study will continue until the last patient entered has completed 24 months in this study. Follow-up visits will occur at 3, 6, 12, 18 and 24 months. A final follow-up visit will occur for all remaining patients at study closure when the final enrolled subject has completed 24 months on study. An Interim Visit must be performed a maximum of 1 month after any change in device settings. Interim visits may also be performed at any time at the principal investigator*s discretion; either between scheduled visits, or after the patient has completed the Month 24 Visit, if the study is still ongoing.

Intervention

Patients will be asked to delivering vagal nerve stimulator treatments using a small magnet each day during the study. For other see page 42 'Schedule of Assessments' of the study protocol and section E6.

Study burden and risks

See Section E of this form.

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 must have enrolled in study SPM-007; including patients who either completed that study or withdrew before completion of that study.

Exclusion criteria

Patients who meet any of the following criteria are not to be enrolled in this study:
* Inability to provide informed consent
* Significant psychiatric illness or substance abuse
* All patients will be excluded who have developed any of these exclusionary conditions during the SMP-007 study, or in the interim between SPM-007 and the Day 0 of SPM-010:
o History of unilateral or bilateral vagotomy
o History of recurrent vaso-vagal syncope episodes
o Known obstructive sleep apnea
o Known history of cardiac rhythm disturbances, atrioventricular block of greater than first degree, or cardiac conduction pathway abnormalities other than isolated right bundle branch block or isolated left anterior fascicle block.

o Significant pharyngeal dysfunction or swallowing difficulties
o Clinically significant vocal cord damage or hoarseness
o Other implanted electrically active medical devices (e.g., cardiac pacemakers, automatic implantable cardioverterdefibrillators)
o Asthma or chronic obstructive pulmonary disease not controlled by medications, or any other disease causing clinically significant dyspnea
o A greater than or equal to 40 pack-year smoking history
o Active peptic ulcer disease
o Patients with a limited life expectancy due to terminal illness.
* If the patient has previously discontinued SPM-007 and greater than 30 days have elapsed since the final visit in SPM-007, the interim history including medical history, adverse events, device deficiencies, and concomitant medications will be assessed to determine if these preclude safe enrollment.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2015
Enrollment:	3
Type:	Actual

Medical products/devices used

Generic name:	Cyberconics VNS system
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	30-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2016
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	NL49869.018.14