BurstDRTM Spinal Cord Stimulation for Refractory Angina Pectoris - a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28539

Source
Nationaal Trial Register

Brief title
BAP Study

Health condition

Refractory Angina Pectoris

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht/Zeist
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Pijngeneeskunde

Intervention

Outcome measures

Primary outcome

To evaluate if BurstDRTM SCS is clinically non-inferior to conventional SCS in patients already implanted with an internal pulse generator (IPG) capable of delivering both conventional and burst SCS

Secondary outcome

To evaluate patient satisfaction and quality of life with BurstDRTM SCS compared to conventional SCS. Gather data in order to calculate the adequate sample size of a future randomised controlled trial.

Study description

Background summary

Rationale: For decades, Spinal Cord Stimulation (SCS) has been used for the treatment of refractory neuropathic and ischaemic pain. In conventional SCS, paraesthesias are induced in the painful area through electrical stimulation of the spinal cord. Recently new stimulation modes became available in which no paraesthesias are perceived resulting in better patient comfort. These novel stimulation modes have gathered evidence in the treatment of neuropathic pain. So far, there are no reports of the appliance of these new modes for ischaemic pain, despite the fact that they are often applied in clinical practice. Therefore, we want to evaluate one of the novel modes, burst stimulation, for the treatment of refractory angina pectoris. We hypothesize burst SCS will be non-inferior compared to conventional SCS in clinical effectiveness with a higher patient satisfaction.
Objective: The main objective of the study is to test if burst SCS is clinically non-inferior to conventional SCS in patients already successfully treated with conventional SCS. The secondary objective of the study is to evaluate patient satisfaction and quality of life with burst SCS. Gathered data will also be used to calculate an adequate sample size for a future randomised controlled trial.
Study design: The study is designed as a prospective pilot study in patients with successful conventional SCS of their refractory angina. Their system will be able to deliver both conventional and burst SCS. Burst stimulation will be available as an extra program, providing patients with the possibility to fall back on their conventional program anytime.
Study population: 10 patients with refractory angina, successfully treated with conventional SCS for at least three months, and who have a system that is also capable of delivering burst stimulation.
Main study parameters/endpoints: Clinical effectiveness of the SCS treatment for refractory angina will be measured with the Seattle angina questionnaire (SAQ) comparing baseline conventional stimulation with burst SCS at 1 month. Patient satisfaction will be measured on a 11 point Numeric Rating Scale and quality of life with the EQ5D.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The extra burden for the participants of this study is one extra follow-up visit after the period of burst SCS. There are no extra risks because their system is able to deliver both conventional and burst SCS. Also burst SCS has proven to be safe in SCS for neuropathic pain. The baseline study parameters will be extracted from the routine questionnaires, which are used in the standard follow-up according to the Dutch Association for Neuromodulation (VvNN). A potential benefit for the participants is that burst SCS results in the same clinical effect with a higher patient comfort due to the absence of paraesthesias.

Study objective

We hypothesize that BurstDRTM SCS will be equally effective in clinical treatment with a higher patient satisfaction compared to conventional SCS in patients suffering from refractory angina.

Study design

Baseline-1 month Burst SCS-evaluation and study exit

Intervention

The study is designed as a prospective pilot study in a cohort of patients already treated with conventional SCS and at least three months of successful treatment of refractory angina. Their device can deliver both conventional and burst SCS. An one month period with burst SCS will be compared to baseline measurements with conventional SCS.
Subjects will be consecutively recruited from a group of patients with refractory angina previously implanted with a SCS system in the Diakonessenhuis Utrecht/Zeist. Based on the IPG lifetime, 10 to 20 patients are expected to come in for routine IPG replacement in 2019. In all patients, this minor surgical procedure will be performed in the Diakonessenhuis. Newly implanted IPGs are able to deliver both conventional and burst SCS.
Based on standard clinical follow-up, baseline primary and secondary measurements will take place before switching to BurstDRTM SCS. Measurements performed after one month of BurstDRTM SCS will be compared to baseline measurements.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- age 18 to 90 of either sex, successfully treated with SCS for refractory angina during at least 3 months
- mentally competent and able to fill in the questionnaires
- implanted with an IPG capable of delivering both conventional and BurstDRTM SCS at least 1 month before study enrolment
- no changes in anti-angina medication in the previous three months
- no procedures like PCI or CABG, nor instability of the clinical signs and symptoms of refractory angina in the previous three months
- the implanted SCS system has no signs of hardware problems (normal lead impedances)
- able to use the remote control Ipod

Exclusion criteria

Subjects who meet any of the following criteria will be excluded from participation in this study:
- signs of instable angina pectoris
- unexplained weight loss in the previous three months
- inability to visit the outpatient department for the follow-up visits
- unable to provide informed consent
- myocardial infarction or unstable angina in the previous three months

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	01-03-2020
Application type:	First submission

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
NTR-new	NL8415
Other	METC AMC : 2019_001

Study results