Feasibility, safety and efficacy of the Freedom* Stimulation System for Peripheral subcutaneous field stimulation (PSFS) application in patients with chronic refractory angina pectoris. A Pilot Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON40864

Source
ToetsingOnline

Brief title
Peripheral subcutaneous field stimulation for chronic angina pectoris

Condition

- Coronary artery disorders

Synonym
longstandig chest pain due to heart vessel disease without further treatment options, refractory angina pectoris

Research involving
Human

Sponsors and support

Primary sponsor: anesthesiologie- onderzoeksbureau
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: angina pectoris, chronic, field stimulation, peripheral

Outcome measures

Primary outcome

Number of angina attacks and use of glyceryl trinitate (GTN) at baseline, 3 months and 12 months

Secondary outcome

•Subject satisfaction, measured by a 5-point subject satisfaction Likert-scale and Patient Global Impression of Change (PGIC), at baseline, 3 months and 12 months

•Quality of life (measured by Seattle angina questionnaire), at baseline, 3 months and 12 months

•Standardized bicycle exercise stress testing, at baseline and at 3 months:

•Feasibility of the Freedom implantation procedure (duration of the procedure, patients acceptance)

•Safety: number of adverse and serious adverse events, device related complications requiring medical intervention, hematomas, infections, dislodgements, loss of stimulation or device related re-hospitalization at 3 months and 12 months

Study description

Background summary

For patients suffering from therapeutic refractory chronic pain spinal cord stimulation (SCS) has been advocated, most often as a last resort. The same accounts for patients with chronic angina pectoris, therapeutic refractory to conventional therapies.
SCS requires meticulous placement of an electrode in the epidural space in the cervicothoracic region, however, placement is not always technically feasible, mostly due to a difficult anatomy. Furthermore, electrode placement is time consuming and associated with all risks of an invasive procedure such as infection and bleeding. Therefore alternative treatment options with a comparable neuromodulatory effect need to be explored, in this case placement of subcutaneous electrodes in the chest region where angina is projected.
Earlier, we demonstrated in an observational pilot study that such a subcutaneous application of the therapy is feasible and effective. When compared to the available literature of SCS, both quality of life and exercise capacity improved significant during follow-up and both outcomes were comparable with SCS.
However, longer follow-up revealed problems with lead migration and subsequent loss of effectiveness in a significant number of patients.
With a recently developed electrode, which has a different design and is approved for refractory chronic spinal pain, we hypothesize that subcutaneous stimulation is as feasible and effective as the previous systems, but the procedure is less cumbersome for both the patient and the surgeon and the lead migration will be much less of a problem.

Study objective

The primary objective is to determine the efficacy of pain control with this type of Peripheral Subcutaneous Field Stimulation (PSFS) at three months and 12 months. The secondary objectives determined at both 3 and 12 months are the assessment of the safety of the procedure, indicated by any intraoperative and postoperative complications such as bleeding, infection, lead migration and other technical problems. Furthermore the feasibility of the implantation and burdens for the patient (such as need for frequent re-programming) will be assessed. Based on the available literature we expect to find at least 50% reduction in angina complaints and subsequent use of short acting nitrate intake

Study design

Interventional trial with medical device.

Intervention

Placemnet of up to three electrodes subcutenously in the ventral part of the chest where the aptient is usually having angina complaints.

Study burden and risks

Following the standard care manner of acting, potential candidates for neuromodulation are referred from the department of cardiology to paincentre of the department of anesthesiology of the UMCG. Eligible patients will be referred to the implanting physician for explanation of the procedure and physical examination. When, after a respite of minimally 2 week , written informed consent is obtained the patient is referred to the preoperative assessment clinic. Prior to the procedure the participants are asked to fill in questionnaires and to undergo standardized bicycle exercise stress testing. Participants are admitted at the day of the procedure to undergo the procedure under local anesthesia, under sterile conditions in an operating room. The decision to continue anticoagulant treatment or not will be done by the cardiologist in charge, based upon patients* characteristics. In our previous pilot study with subcutaneous stimulation, in which the implantation procedure required significant more tissue manipulation, when compared to the present electrode, no bleeding complications where noted. Thus, we expect no extra risk for (late) bleeding. Nevertheless, an ultrasound-scan will be performed at the end of the procedure and the patient will stay overnight for monitoring. The scan is repeated prior to release from hospital to detect any formation of hematoma. In the following period, ongoing bleeding or any sign of wound infection may require surgical revision and antibiotic therapy if indicated. In case of lead migration and / or ineffective stimulation, removal of the lead is not necessary, since the lead is not expected to cause long-term problems and does not interfere with, for instance, MRI, if indicated. However, lead(s) will be removed at the express whish of the patient. To remove the lead only a small surgical procedure is required, which usually can be done in an outpatient setting.
One week after the procedure all participants will return for control of the surgical wound and possible adaptation of the stimulator settings. In case of insufficient coverage or unpleasant paresthesia an earlier return to the hospital might be necessary for re-programming. All patients are asked to document, in a diary, the number of episodes of angina, use of stimulation and use of GTN, during the week preceding the follow-up visit at 3 months and 12 months. At the 3 months follow-up visit the bicycle exercise-test will be repeated

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-stable angina pectoris, Canadian Cardiovascular Society scale (CCS) class III- IV
- therapeutic refractory for at least 3 months
-angina in the retrosternal and precordial area
-angiographically documented coronary artery disease
-demonstrated ischemia (by exercise test, 48h ECG registration, nuclide scan or PET)
-optimal anti-angina medication for >= 1 month
- age >= 18 years

Exclusion criteria

-Short life expectancy (i.e. < 1 year)

-Cardiac syndrome X (i.e. small vessel disease or microvascular angina pectoris)
-Vaso-spastic angina pectoris
-Myocardial infarction * 3 months.
-Severe heart failure NYHA class III-IV
-Significant valve insufficiency (grade IV/IV) or valve stenosis
-Treatment with TENS in the 2 weeks prior to start of the study (i.e. PSFS implantation)
-Severe cutaneous sensory disturbances such as allodynia, hypoesthesia in area where angina is experienced.
-Child bearing potential
-Inability to perform exercise tests
-Pacemaker dependency.
-Inadequately regulated hypertension
-Inadequately regulated diabetes mellitus
-Psychological inability that may lead to significant instruction or compliance-problems
-Inappropriate use of drugs (opiates, cocaine etc) or alcohol by the patient.
-The presence of other neurostimulation device(s)

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):	20-01-2015
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	implantable neurostimulation device
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	18-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-10-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL50393.042.14