Spinal Cord Stimulation for Vasospastic Angina Pectoris - a prospective study

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

Summary

ID

NL-OMON53627

Source
ToetsingOnline

Brief title
VAP study

Condition

- Coronary artery disorders

Synonym
Angina Pectoris - Chest Pain

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Angina Pectoris, ANOCA, Spinal Cord Stimulation, Vasospastic

Outcome measures

Primary outcome

Primairy endpoint is the *Seattle Angina Questionnaire* (SAQ) at month 1 and 3.

Secondary outcome

Secundairy endpoints are presentation at ER and patient satisfaction measured

on a 11 point Numeric Rating Scale and quality of life with the EQ5D at month

1, 3 and 6 months, compared to baseline. Endpoints of the acetylcholine test

are changes in coronary flow and coronary diameter compared to baseline.

Study description

Background summary

According to the 2020 Dutch guideline on chest pain (AP) without obstructive coronary artery disease, 70% of female and 30% of male patients undergoing a coronary angiogram, have no obstructive coronary artery disease. In the majority of patients the complaints are based on vascular dysfunction, including epicardial vascular spasms (EVS). For patients who are refractory to drug treatment, spinal cord stimulation (SCS) can be a treatment option. SCS is used for the treatment of refractory neuropathic and ischaemic pain. In recent studies the use of SCS is proven for refractory angina pectoris, but the group with refractory vasospastic angina pectoris (rVSA) predominantly seen in women with invalidating impairment of quality of life, is overlooked, as no evidence of obstruction is found at CAG. With this study we hypothesis that SCS is effective in reducing the number and intensity of angina attacks, reducing nitrate use, reducing inhospital treatment and ER presentations, thereby reducing medical costs, and above all, increasing quality of life.

Study objective

The main objective of this study is to evaluate the clinical effects of SCS on the number and intensity of VSA attacks. Secondary objective is to objectivate the effects of SCS on coronary spasms during the provocative acetylcholine

test, and assess medical costs, patient satisfaction and quality of life.

Study design

Prospective study in two phases. Phase 1: evaluation of clinical effectiveness. Phase 2: evaluation of SCS on vascular spasms during acetylcholine provocation test.

Intervention

Implantation with a SCS defice with one or two lead(s) in the epidural space of T1 to T4, active elctrodes depending on mapping of the painfull area, under local anesthesia and sedation. Acetylcholine test during CAG at 4 to 6 months.

Study burden and risks

SCS is proven to be safe for neuropathic and ischaemic pain and is widely used in clinical practice. With the positive results of an ongoing clinical trial for refractory coronary angina, we estimate the efficacy of SCS to be around 80-90% in reducing VSA attacks with 50% after 3 months and therefore very effective in otherwise refractory drug treatment regiments. Furthermore, baseline study parameters will be extracted from the routine questionnaires and during visits to the outpatient clinic.
Only in patients who specifically consent to it, an additional acetylcholine test 4 to 6 months after SCS implantation during coranary angiography (CAG) is performed. This is an additional CAG procedure under local anesthesia which potentially provokes VSA. Done by experienced personal this is a safe test with a complication risk of 0-0.7% for severe cardiac complications, comparable to coronary angiogram with FFR measurement.
A potential benefit for the participants is that SCS results in reduction of VSA attacks, reduction of nitrate use, less presentation at an ER, an improved quality of life, and acceptation as standard treatment and therefore insured treatment for the overall patientgroup.

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

- age 18 to 90 of either sex
- VSA is objectivated with a provocative acetylcholine test
- mentally competent and able to fill in the questionnaires
- refractory VSA defined as chest pain with a maximum tolerated dosage of calcium antagonists, long acting nitrates, and ACE for a minimum of three months
- no procedures like PCI or CABG, nor instability of the clinical signs and symptoms of refractory angina in the previous three months
- absence of obstructive coronary artery disease evident in a main coronary artery (diameter stenosis<50%, iFR>0.89, or FFR >0.80)
- able to use the remote control of the SCS system

Exclusion criteria

- inability to visit the outpatient department for the follow-up visits
- unable to provide informed consent
- myocardial infarction in the previous three months
- implanted pacemaker or ICD incompatible with SCS
- indication for ongoing anticoagulation 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):	22-02-2024
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Spinal Cord Stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-10-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2024
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
ClinicalTrials.gov	NCT06176391
CCMO	NL79947.018.21