Peripheral subcutaneous field stimulation for angina pectoris

No registrations found.

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

Summary

ID

NL-OMON27567

Source
Nationaal Trial Register

Health condition

chronic angina pectoris

Sponsors and support

Primary sponsor: University medical center groningen
Source(s) of monetary or material Support: no funding

Intervention

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

Study objective

The primary objective is to determine the efficacy of angina control with this type of Peripheral Subcutaneous Field Stimulation (PSFS) at three months and 12 months. This will be assessed in a patient diary by the number of angina attacks and the required doses of nitrates in the week before the scheduled control visit. 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

12 months

Intervention

Patients will receive up to three subcutaneous electrodes (Freedom-4®) in order to cover the area of their angina complaints

Contacts

Public
Hanzeplein 1
R. Spanjersberg
Groningen 9700 RB
The Netherlands

+31 (0)50 3611158
Scientific
Hanzeplein 1
R. Spanjersberg
Groningen 9700 RB
The Netherlands
+31 (0)50 3611158

Eligibility criteria

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.
- skin infections in the area where angina is felt
-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
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2015
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-02-2015
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	NL4938
NTR-old	NTR5039
Other	: Free RAP 1

Study results