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A study to compare spinal cord stimulator implantation with laser treatment of the heart in patients with chronic angina

Submission date	Recruitment status	[_] Prospectively registered
07/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/03/2008	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2.2 dated 5 January 2004

Study information

Scientific Title
An open label, single-centre, randomized trial of spinal cord stimulation vs percutaneous myocardial laser revascularization in patients with refractory angina pectoris: the SPiRiT trial

Acronym
SPIRIT

Study objectives
Refractory angina pectoris leads to significant morbidity. There is an increasing group of patients with 'refractory angina pectoris' who are unsuitable for conventional revascularization by coronary artery bypass surgery or percutaneous intervention. This patient group often have significant disability, with limiting symptoms, multiple medications, and frequent hospital admissions.

Treatment options include percutaneous myocardial laser revascularization (PMR) and spinal cord stimulation (SCS). The primary objective of this study was to compare the effect of SCS vs PMR on treadmill exercise time on a modified Bruce protocol over a period of 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval was obtained from the Huntingdon Local Research Ethics Committee, UK, prior to study commencement, on 15 August 2000 (ref: H00/557)

Study design
Prospective, open, parallel, single-centre, randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic angina pectoris

Interventions
Trial patients were randomised to either Spinal Cord Stimulation System implant (SCS) or Percutaneous Myocardial Laser Revascularisation (PMR).

The Spinal Cord Stimulation System used for this trial was a Medtronic fully implantable SCS systems. Either Itrel 3 or Synergy implantable generators were used. The spinal cord stimulation lead was chosen by the investigator from any Medtronic commercially available lead approved for use in refractory angina pectoris. The implant was performed according to the instructions in the technical manuals accompanying the devices. The lead was placed such that adequate /optimal paraesthesia was obtained in the area of angina pain. When adequate paraesthesia coverage was obtained the physician went on to permanent implant of the pulse generator. Proper patient education both pre and post implant of the device is essential. The investigator was responsible for adequately and regularly checking the integrity of the system at 3 months, 12 months and then annually. The stimulator should be used prophylactically by the patient for a minimum of 3 hours per day (for example: 3 times per day for a duration of 1 hour each). However, there is no upper limit and the patient may use the device as much as needed. Parameters for this stimulation vary from patient to patient. Therefore, the physician and patient need to work together to establish an effective and tolerable level. The stimulator should also be used at time of anginal attack to treat the pain. A higher level of stimulation may be used for this acute treatment. The maximum tolerable amplitude should be set for such use. However, it is necessary to assure that this level is not uncomfortable or painful.

For this trial any commercially available Percutaneous Myocardial Revascularisation could be used. An optical fibre is inserted via the femoral artery under local anaesthesia and passed up into the left ventricle. Energy from a Ho:YAG laser is applied to the endocardial surface of the myocardium to vaporise the myocardial tissue and create channels from the endocardial surface into the myocardium. The co-axial system allows the laser to be manipulated in 3 planes giving access to the whole of the left ventricle. The laser position is monitored by fluoroscopy in orthogonal views. Once the position of the laser has been checked in both views, the laser is fired. Two bursts of the laser are used to create a channel 4-6 mm deep, in the myocardium, except in the apex where only one burst is used. The position is marked in both views on acetate sheets attached to the fluoroscopy monitors. Laser channels are created at a minimum of 1 cm apart, and are placed to cover the target region. Typically 10-15 channels are being made.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Total exercise time on a modified Bruce protocol (ETT) at 12 months after SCS compared with PMR. In this study, all tests were terminated by the subject. Both SCS and PMR aim to reduce the frequency and severity of angina, and exercise tolerance is a comparatively objective method of measuring angina-free functional capacity.

Secondary outcome measures
1. Time to patient-reported angina during exercise test
2. Angina class as measured by the Canadian Cardiovascular Score angina scale
3. Morbidity and mortality
4. Safety profiles of each therapy
5. Health-related quality of life was assessed using questionnaires administered at 3, 12, 24 and 36 month follow-up (disease-specific Seattle Angina Questionnaire, the generic Short Form 36 health survey , and EuroQoL questionnaires)

Overall study start date
01/12/2000

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Patient with limiting angina (Canadian Cardiovascular Society [CCS] III or IV) despite maximally tolerated medical therapy
2. Documented coronary artery disease (within the last 9 months prior to baseline), which is unsuitable for conventional revascularisation techniques
3. Patient has documented reversible ischaemia on nuclear scan (Tc-99 sestamibi)
4. Patient is limited in daily activities, primarily exercise capability, by their anginal pain
5. Age 18 or older
6. Patient must understand the therapy and give informed consent
7. Patient must be available for appropriate follow-up times for length of study
8. Non-pregnant women (only women who are post menopausal, surgically sterile or those of child bearing potential who are using an acceptable method of contraception) as safety for use of SCS during pregnancy or delivery has not been established. Acceptable methods of contraception include the following:
a. Barrier type devices (e.g. female condom, diaphragm and contraceptive sponge) used only in combination with a spermicide
b. Intrauterine devices (IDUs)
c. Oral contraceptive agent
d. Depro-ProveraTM (medroxyprogesterone acetate)
e. Levonorgestrel implants
f. Naturally sterile (amenorrheic for at least 1 year) in patients over 50
Note: Abstinence, the rhythm method or contraception by the partner alone are NOT acceptable methods of contraception

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
68

Key exclusion criteria
1. Patient who is not a candidate for surgical implantation of the spinal cord stimulation system, and/or not a candidate for a PMR procedure and/or unable to use the SCS device appropriately

for treatment
2. Patient who has had one or more major cardiac events within the last 2 months
3. Patient with a myocardial wall thickness <8 mm in the ischaemic area to be treated as verified by echocardiography
4. Patient with extensive peripheral vascular disease that precludes vascular access required for PMR
5. Patient on intravenous therapy to control their symptoms
6. Patient who is unlikely to survive for more than 12 months due to non cardiac condition e.g. malignancy
7. Patient who has other diseases that are considered of greater clinical significance than the angina pectoris (e.g. inadequately controlled diabetes mellitus, heart failure) that would impact the ability of the clinician to adequately assess the incremental effects of the trial treatment
8. Patient with ejection fraction of less than 30% as verified by echocardiography
9. Patient with cause of angina other than coronary artery disease (e.g. syndrome "X" patient)
10. Patient who is unable to perform treadmill exercise test per protocol
11. Patient who was previously enrolled in this study, or is currently in another clinical study, which will interfere with this protocol
12. Patient who has had spinal cord stimulation (SCS) therapy, a transmyocardial laser revascularization (TMLR) or PMR procedure in the past
13. Patient with an implanted pacemaker or defibrillator
14. Patient who has medical conditions which may require Magnetic Resonance Imaging (MRI)
15. Patient with a history of dementia or other persisting mental disorders significantly interfering
with ability to cooperate or comply with the requirements of the study or comprehend informed consent
16. Patient with history of alcohol or drug abuse

Date of first enrolment
01/12/2000

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Papworth Hospital NHS Foundation Trust
Cambridge
United Kingdom
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Sponsor information

Organisation
Medtronic Sàrl (Switzerland)

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Sponsor type
Industry

Website
http://www.medtronic.com

ROR
https://ror.org/04pf17v09

Funder(s)

Funder type
Industry

Funder Name
This study was sponsored by Medtronic SA, who were responsible for funding of the trial related investigations such as perfusion scans and treadmill tests, research staff for data collection and travelling expenses for the subjects. The sponsor had no role in study design, data collection and interpretation, or in the decision to submit the above report for publication.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/05/2006		Yes	No