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The RASCAL study (refractory angina spinal cord stimulation and usual care)

Submission date
28/02/2011

Recruitment status
No longer recruiting

Registration date
12/04/2011

Overall study status
Completed

Last Edited
05/12/2017

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Coronary heart disease (CHD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CHD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). When arteries are blocked or narrowed, the heart does not receive enough blood to function properly, which can cause pain and tightness in the chest (angina). Refractory angina (RA) is a form of angina where usual treatments such as coronary artery bypass grafts (an operation in which a blood vessel from another part of the body is attached to the coronary artery above and below the blocked or narrowed area so that blood is diverted around the blockage) are ineffective. As RA is so difficult to treat, it can be extremely disabling for patients, involving frequent hospital visits and a reduced quality of life. Spinal cord stimulation (SCS), sometimes called neuromodulation, is a treatment used for people with long-term (chronic) debilitating pain conditions. It involves implanting a 'pacemaker-like' box under the skin and connecting it using leads and electrodes to the nerves of the spine (spinal cord) at chest level. Although a small number of UK centres currently provide this treatment, it has not yet become accepted practice in the treatment of RA. The aim of this study is to look at the effectiveness of SCS in the treatment of patients with RA.

Who can participate?
Adults suffering from CHD with RA.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group (intervention group) undergo an operation so that the spinal cord stimulator (SCS) device can be implanted and connected to the spinal cord. The participants in this group also continue to receive usual medical care, including pain relief medications and educational sessions with a pain consultant. Participants in the second group receive normal care alone, which consists of pain relief medications, educational sessions with a pain consultant and the option to use a TENS machine (a device designed to provide pain relief using electrical stimulation to the skin). At the start of the study and then again after six months, participants in both groups complete a number of questionnaires in order to assess their pain levels and quality of life.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2011 to July 2013

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2.0/ 20Jan11

Study information

Scientific Title
A multicentre randomised controlled trial of Spinal Cord Stimulation plus usual care vs. usual care alone in the management of Refractory Angina: a feasibility & pilot study

Acronym
RASCAL

Study objectives
Our overarching hypothesis is that spinal cord stimulation (SCS) plus usual care will have superior clinical and cost-effectiveness compared to usual care alone in Refractory Angina (RA) patients. A pilot study is first proposed to assess the feasibility of a definitive trial to address this hypothesis. The pilot study will randomise RA patients to SCS ('SCS group') plus usual care or usual care ('UC group') alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside REC 1 - approval pending as of 02/03/2011

Study design
Pragmatic multi-centre pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Refractory angina

Interventions
Participants will be randomised to receive either a spinal cord stimulator (SCS) with usual care or to receive usual care alone.

One group will therefore have a SCS implanted following a successful trial. Other interventions include exercise tolerance testing, questionnaire completion, physical examination, vital signs recording, females of childbearing potential will undergo pregnancy testing, medical history recording and concomitant and cardiology medication assessment.

Participants allocated usual care, may receive educational sessions with a pain consultant, transcutaneous electrical nerve stimulation (TENs) machines, serial thoracic sympathectomy and oral/systemic analgesics and adjuvant analgesia.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
HRQoL as measured using the disease-specific measure the Seattle angina questionnaire (SAQ) UK version. We expect the SAQ to be the primary outcome in the definitive trial.

Secondary outcome measures
1. Intake of angina medications and angina attacks
2. Exercise capacity (at baseline and 6-months only)
3. Complications and adverse events
4. Healthcare utilisation (e.g. cardiac specific hospitalisations and primary care visits, management of complications/adverse events)
5. Generic measures HRQoL will be assessed using the EuroQol (EQ-5D) and Short Form -36 (SF-36) questionnaires

Overall study start date
01/05/2011

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Limiting angina despite optimal anti-angina therapy
2. Canadian Cardiovascular Society Functional Classification of Angina (CCS) Class III and IV
3. Angiographically documented coronary artery disease (CAD)
4. CAD not suitable for revascularisation in the opinion of the referring cardiologist /cardiothoracic surgeon
5. Satisfactory multidisciplinary assessment in accordance with British Pain Society (BPS) guidelines for SCS
6. Demonstrable ischaemia on functional testing

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Forty-five (45) Participants over 3 sites.

Key exclusion criteria

1. Presence of pacemaker or implanted defibrillator that is incompatible with SCS
2. Patient refusal to participate in the study
3. Presence of co morbidity considered by the assessing clinician to overshadow the effect of the angina or render them an unsuitable candidate for neuromodulation (e.g. advanced spinal disease or deformity)
4. Poor cognitive ability
5. Ongoing anticoagulation therapy, where anticoagulants cannot be safely discontinued without jeopardising patient safety

Date of first enrolment
01/05/2011

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Tees Hospitals NHS Foundation Trust
Middlesbrough
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TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	22/02/2013		Yes	No
Results article	results	01/01/2016		Yes	No