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Aneurysm care trial - cardiac rehabilitation after aneurysm repair

Submission date	Recruitment status	[_] Prospectively registered
05/06/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/06/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
An aortic aneurysm is a swelling of the largest blood vessel in the body in the chest or the abdomen. This denotes a weakness that, if allowed to become large enough, puts the patients at risk of the blood vessel bursting. If this happens it is usually fatal so, if at all possible, they are repaired surgically before this occurs. Arterial disease affecting the heart is unusually common in survivors of aortic aneurysm surgery and heart disease is the major cause of death and complications following surgery in these patients. Cardiac rehabilitation (CR) is a structured programme using lifestyle measures, exercise and education, which improves the life expectancy of patients with heart disease and is provided through a well-developed national infrastructure. It is not currently known if survivors of aneurysm repair would have improved long-term survival if enrolled in CR rather than standard care. This small-scale study is aiming to find out how many survivors of aneurysm repair would agree to participate in a study of rehabilitation therapy and to establish their attendance once enrolled.

Who can participate?
Patients who undergo aneurysm repair operation and are discharged from the hospital during the study recruitment period.

What does the study involve?
Patients will first be made aware of the study when they attend clinic appointments prior to surgery, and will be provided with an information leaflet to take away and read - it will be made clear that entry into the programme is not compulsory, but that if they consent adherence to the programme is important. Once the patient has successfully undergone their aortic aneurysm repair and are fit for discharge, they will be asked whether or not they would like to participate in the study. If they agree, they will be randomly allocated to one of two groups: the treatment group or standard care. Those that decline to be included in the study will be asked to complete a short questionnaire to find out the reasoning behind choosing not to take part in such a study (e.g. travelling, lack of understanding etc.). The patients in the standard care group will receive standard surgical follow-up and routine primary care management after surgery. The patients in the treatment group will attend the structured, established cardiac rehabilitation programme. The programme will typically start 4-6 weeks after their surgery and involves attending a session lasting 1-2 hours once a week for 6-8 weeks. However, in instances where it is deemed the

patient will benefit from longer in the programme this is extended. Once a week there is an education session run after the exercise class to advise about other lifestyle factors, dietary advice and to give advice about medication (a pharmacist attends this session). We will be conducting a series of additional blood tests to both groups of patients at three points during the study: at the start, after 12 weeks and after 6 months. We will also be taking saliva and urine samples at each of these time points to look for potential kidney disease and adherence to smoking cessation, and also conducting echocardiograms (heart scans) at each time point to assess the functioning of the heart.

What are the possible benefits and risks of participating?
CR is a well-established, safe programme, which is conducted under close supervision. The only burden will be attending the rehabilitation classes. Those who are unable to attend the sessions will be excluded from the study. However, if a larger study were to be deemed possible in the future it is possible provision could be made for them to have rehabilitation at home. There is a risk that patients enrolled in treatment as usual will not receive therapy in line with the national guidelines (NICE) from their GPs. In cases where this is found, we will write to the patient's GP and inform them of the discrepancy with the NICE guidelines. This will ensure that the risk to patients is minimised.

Where is the study run from?
This study is being carried out at two sites in the UK St Georges Vascular Institute, London (lead centre) and University Hospitals of Leicester.

When is the study starting and how long is it expected to run for?
The study started in April 2014 and runs until October 2015.

Who is funding the study?
British Heart Foundation (BHF), UK.

Who is the main contact?
Mr Peter Holt (Consultant and Senior Lecturer of Vascular Surgery), St Georges Vascular Institute, London
Mr Matt Brown (Consultant Vascular Surgery), Leicester

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16287

Study information

Scientific Title
Pilot randomised controlled trial of cardiac rehabilitation vs standard care after aortic aneurysm repair to reduce adverse cardiovascular events

Study objectives
Our study hypothesis is that at least 60-70% of patients surviving aneurysm repair will agree to trial enrolment into a study of CR after elective aneurysm repair with a true figure of 70-80%. We are also aiming to establish if a minimum of 60-70%, with a true value of 75-90%, of patients will attend all scheduled CR sessions in those randomised to the CR limb of the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/0395; First MREC approval date 21/02/2014

Study design
Randomised; Interventional; Design type: Prevention, Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied

Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Cardiac Rehabilitation: Patients undergoing elective aortic aneurysm surgery will be randomised. The 'intervention' limb will enter into a cardiac rehabilitation programme surgery.
Care as Usual, Normal post-operative care; this will mean standard surgical follow-up and routine primary care management post surgery.
Follow-up length: 6 month(s); study entry: registration and one or more randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The number of patients surviving aneurysm repair that agree to enroll in an RCT of rehabilitation vs standard therapy, to establish the proportion of those approached who agree to consent to entry to the CR programme
2. The level of compliance with cardiac rehabilitation (CR) therapy and attendance of the scheduled sessions

Secondary outcome measures
1. Time to death
2. Time to first cardiovascular event after aneurysm repair. This is a composite endpoint including non-fatal myocardial infarction, stroke, revascularization and nontraumatic amputation. The revascularization endpoint includes strictly defined procedures (coronary artery bypass graft surgery, percutaneous coronary interventions and percutaneous coronary interventions) and peripheral vascular procedures (embolectomy, bypass and angioplasty). In the absence of relevant COMET outcomes, this outcome measure mirrors the composite cardiovascular endpoint measured for previous randomised RCTs of cardiovascular risk reduction. Statistically adjusted analysis of the total number of events during follow-up will eventually minimise the risk that reporting only a 'composite cardiovascular disease event' endpoint may mask a treatment effect or ignore competing risk; for example, the intervention reducing the risk of one event but increase the risk of another.
3. Intermediate phenotypic markers of cardiovascular risk measured at enrolment, 12 weeks after entry to CR and 6 months after entry to CR: serum lipids (total cholesterol, HDL and LDL), systolic and diastolic blood pressure, HbA1C, BNP, Troponin, hsCRP, Fibrinogen, Homocysteine, urate, eGFR, serum insulin levels, and echocardiographic measure of cardiac function. We will also be testing for urinary microalbuminuria at enrolment, 12 weeks and 6 months.
4. Indicators of patient behavior and lifestyle/biometrics: waist:hip ratio and waist circumference, BMI, ankle-brachial pressure index (ABPI) and toe pressures. Smoking cessation outcomes will include: salivary cotinine, expiratory carbon monoxide, 'prolonged abstinence', and attendance at NHS stop-smoking services.
5. Quality of Life: EQ5D5L questionnaires will be administered at enrolment, 12 weeks after entry to CR and 6 months after entry to CR.
6. Cost-Effectiveness: Mean costs and Quality Adjusted Life Years will be compared on an intention-to-treat basis. The perspective will be the NHS and PSS. The analysis will include hospital re-admissions and pharmaceuticals. Unit cost will be obtained from the published literature.

Overall study start date
01/04/2014

Completion date
01/10/2015

Eligibility

Key inclusion criteria
All patients who undergo elective repair of a thoracic or abdominal aortic aneurysm at St George`s Vascular Institute or Leicester Royal Infirmary and are discharged alive from hospital during the study recruitment period will be eligible for entry

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 84; UK Sample Size: 84

Total final enrolment
68

Key exclusion criteria
1. Under age 50
2. Unable or unwilling to consent
3. Deemed not medically fit enough for rehab programme by lead CR nurse
4. Unwilling or unable to attend the CR sessions
5. Anyone undergoing expedited or emergent surgical intervention for ruptured or symptomatic aortic aneurysms

Date of first enrolment
01/04/2014

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Georges Hospital
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
St George's University of London (UK)

Sponsor details
Cranmer Terrace
London
England
United Kingdom
SW17 0RE

Sponsor type
University/education

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF), Grant Codes: PG/13/98/30490

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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	15/04/2015		Yes	No
Basic results		29/09/2019	30/09/2019	No	No
HRA research summary			28/06/2023	No	No