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Feasibility of early cardiac rehabilitation after coronary artery bypass grafting

Submission date
08/01/2019

Recruitment status
No longer recruiting

Registration date
24/01/2019

Overall study status
Completed

Last Edited
15/05/2023

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
In the UK, heart operations have steadily increased since 2010. Of 36,134 operations performed in 2013, 17,630 were isolated coronary artery bypass grafting (CABG). Following CABG, patients currently attend their first outpatient review six weeks after hospital discharge, where recovery is assessed and fitness to commence cardiac rehabilitation (CR) is determined. CR is then started from eight weeks. There is no research to support the timings of either the outpatient check-up or the start of cardiac rehabilitation. The long interval before postoperative review and CR extends the period of vulnerability and inactivity for patients. The aim of this study is to examine the feasibility of bringing forward outpatient review and CR, in order to facilitate recovery, physical fitness and quality of life.

Who can participate?
Patients 18 to 75 years of age undergoing a planned CABG through a median sternotomy

What does the study involve?
Half of the participants are randomly assigned to a new shortened pathway including a postoperative review three weeks after hospital discharge, followed by commencement of CR from four weeks. The remainder continue with usual treatment. CR for both groups involves exercise classes once or twice a week for 8 weeks, and fitness tests. Patients then have a final assessment at 26 weeks, with clinical examination, fitness and breathing tests, and completion of a general health questionnaire. Outcomes are measured through a variety of standard clinical tests as well as questionnaires. Additionally, data is collected through interviews, diary entries and focus group meetings with consenting participants and clinical staff. Patients' and staff experiences, patient fitness levels, delivery of the trial, quality of life and costs associated with each pathway are all analysed.

What are the possible benefits and risks of participating?
Individual participants may not benefit directly from this research but the information gained from this study may help to answer the question as to whether one of these treatments pathways is better than the other. There are no foreseen areas for clinical concern. In the context of lack of robust evidence to determine the best time frames for postoperative review and CR, risks are not increased through participation in the study.

Where is the study run from?
1. East Yorkshire Cardiothoracic Centre (UK)
2. James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2018 to July 2020

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

Who is the main contact?
1. Dumbor Ngaage
2. James Illingworth

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT03551015

Protocol serial number
40546; PB-PG-0317-20047

Study information

Scientific Title
Feasibility study of early outpatient review and early cardiac rehabilitation after coronary artery bypass grafting: mixed methods research design

Acronym
FARSTER

Study objectives
An early postoperative outpatient review followed by early commencement of cardiac rehabilitation is feasible, and would lead to quicker recovery of physical fitness and better quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Derby Research Ethics Committee, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, Tel: +44 (0)207 104 8109 / (0)207 104 8237, Email: NRESCommittee.EastMidlands-Derby@nhs.net, 10/01/2019, REC ref: 18/EM/0391

Primary study design
Interventional

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

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Specialty: Surgery, Primary sub-specialty: Cardiothoracic Surgery; Health Category: Cardiovascular; Disease/Condition: Diseases of arteries, arterioles and capillaries

Interventions
Participants will undergo 1:1 randomisation to either: current (control arm) or the proposed pathway (intervention arm). Randomisation will be undertaken using a centralised randomisation service provided by a York Trials Unit statistician not involved in recruiting patients, and will be stratified by site using randomly permuted variable block sizes.

Control (current practice): postoperative outpatient review 6 weeks after hospital discharge, followed by commencement of cardiac rehabilitation from 8 weeks.

Intervention: postoperative outpatient review 3 weeks after hospital discharge, followed by commencement of cardiac rehabilitation from 4 weeks.

The structure of outpatient review and cardiac rehabilitation will be the same for both arms of the trial, as in current practice, specifically:
1. First postoperative outpatient review: Specialist surgical team will perform postoperative outpatient clinical review, as is standard practice, for all study patients. Postoperative history, clinical examination including sternal stability assessment, chest x-ray, electrocardiogram and medication review will be undertaken and, patients that are certified fit would be referred to cardiac rehabilitation programme. This review will take place at six weeks post hospital discharge in the control arm, and at three weeks in the intervention arm.
2. Outpatient exercise-based cardiac rehabilitation (CR): Patients referred for CR will be offered a comprehensive programme. A first appointment would be made with a cardiac specialist nurse who provides the patient with advice and leaflets on cardiac risk factor reduction. This will typically include information on medication, diet, exercise and physical activity as well as psychosocial wellbeing and smoking cessation. Patients will be invited to a group education session on cardiac risk factor reduction. This will be delivered by specialist cardiac rehabilitation staff. At this first appointment, referral to other healthcare professionals such as specialist counsellors, pharmacists and dieticians may also be considered when necessary. Unless contraindicated, referral to the exercise component of the CR programme will be made. Before joining the CR exercise class, patients will receive a holistic assessment from a specialist physiotherapist or exercise professional. This will involve exercise testing using the incremental shuttle walk test (ISWT). This baseline test will help to personalise exercise prescription for each patent. Following this assessment, patients will be enrolled in exercise programmes. CR exercise training will consist of supervised low-to-moderate intensity exercise performed weekly or twice a week for eight weeks, as is usual practice. Exercise will be prescribed according to standards published by the British Association for Cardiac Prevention and Rehabilitation and, the Association of Chartered Physiotherapists in Cardiac Rehabilitation. Exercise training will be performed in a gym-like environment with other patients. Interval circuit training is the most commonly prescribed mode of exercise with each individual exercise programme tailored to patients' specific needs and fitness level. The following equipment will be used; heart rate monitors, treadmill, static bikes, and hand weights. At the end of CR, a reassessment, including exercise testing using incremental shuttle walk test will be conducted. The pre and post CR tests will be recorded. A discharge letter would be sent to patients' General Practitioners summarising their treatment. The control arm will commence CR at 8 weeks as is the current practice, while the intervention arm will start at 4 weeks.

Intervention Type
Other

Primary outcome(s)
The feasibility of delivering outpatient review three weeks after discharge post-CABG, followed by CR from four weeks, assessed using:
1. Recruitment rates and drop-out to follow-up: recruitment rates measured by summarising number of patients screened, eligible, consenting and randomised during the 5 month recruitment period, and drop-out to follow-up measured by number of questionnaires completed at week 4 or 8 (pre-CR), week 12 or 16 (post-CR), and 6-months post randomisation
2. Compliance to treatment group allocation, measured by the number of participants attending their outpatient review appointment and number of Cardiac Rehabiliation sessions attended
3. Acceptability of patient recruitment, early outpatient review and CR to patients, clinicians and NHS organisations, measured via face-to-face interviews with a sample of participants at

outpatient review appointment (3 weeks or 6 weeks post randomisation and 6 month follow-up appointment) and focus group(s) with research nurses and clinical staff at end of 6-month follow up period. Diaries will also be completed by participants (throughout their 8-week cardiac rehabilitation period), Research nurses (throughout the recruitment phase) and Cardiac rehabilitation staff (for the period study participants are attending cardiac rehabilitation)

Key secondary outcome(s)
1. Physical fitness assessed by dynamic testing with incremental shuttle walk test (ISWT) at commencement and end of CR, and 6 months after surgery
2. Cardiopulmonary fitness assessed by cardiopulmonary exercise testing (CPET) at baseline and at 6 months, for 25 patients in each study group
3. Quality of life assessed with EuroQol five dimensions (EQ-5D-5L) at beginning of the study, end of CR and 6 months after surgery
4. 30- and 90-day mortality, surgical site complications and hospital readmission rates: data collected through outpatient review appointment (3 or 6 weeks), the final assessment (6 months) and AE/SAE reporting. Any such events recorded will be broken down into 'before first appointment' and 'between first appointment and 6 months assessment' and summarised by specific event (i.e. hospital readmission rates).
5. Costs or cost savings associated with the proposed pathway: a full cost-effectiveness analysis will not be undertaken as part of this feasibility study; rather, the work will identify the data, and the feasibility of collecting the data (at week 4 or 8 (pre-CR), week 12 or 16 (post-CR), and 6-months post randomisation), needed for an economic analysis of a full scale trial

Completion date
15/07/2020

Eligibility

Key inclusion criteria
1. Patients undergoing elective and urgent CABG
2. Having full median sternotomy
3. Capable of giving Informed consent
4. 18 to 75 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment

50

Key exclusion criteria
1. Body Mass Index greater than 40kg/m2
2. Heart failure with left ventricular ejection fraction of <30%
3. Early postoperative sternal wound complications such as infection and sternal instability
4. Postoperative complications resulting in prolonged hospital stay greater than 14 days after surgery

Date of first enrolment
20/05/2019

Date of final enrolment
20/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Yorkshire Cardiothoracic Centre
Castle Hill Hospital
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Kingston-Upon-Hull
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HU15 6JQ

Study participating centre
James Cook University Hospital
Marton Road
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TS4 3BW

Sponsor information

Organisation
Hull University Teaching Hospitals NHS Trust

ROR
https://ror.org/01b11x021

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Jenny Roche, trial statistician (jenny.roche@york.ac.uk). The trialists shall make data available to the scientific community with as few restrictions as feasible, while retaining exclusive use of the data until the publication of major outputs. Consent will be obtained from participants to share data anonymously with other researchers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/05/2023	15/05/2023	Yes	No
Protocol article	protocol	29/12/2019	01/12/2020	Yes	No
HRA research summary			26/07/2023	No	No