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Can an exercise programme before cardiac surgery increase patient fitness and improve surgical outcomes?

Submission date
30/09/2019

Recruitment status
No longer recruiting

Registration date
24/10/2019

Overall study status
Completed

Last Edited
25/05/2023

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
More than 35,000 patients undergo cardiac surgery in UK every year. Around 10 – 40% of these patients suffer from post-operative complications. It is well known that patients with more health problems and those who are less active are more likely to have complications during and after surgery and may take longer to recover from their surgery.
An exercise programme carried out in the weeks leading up to surgery is called prehabilitation and exercise carried out after surgery is called rehabilitation.
The purpose of this trial is to find out if a prehabilitation programme carried out in the weeks leading up to heart surgery can improve fitness before surgery and if this results in better outcomes for patients after surgery.

Who can participate?
Patients aged over 18 listed for elective cardiac surgery at the James Cook University Hospital

What does the study involve?
Eligible patients will be asked to complete a number of physical assessments and questionnaires and will be put into 1 of 2 groups, Group 1 will be given an exercise programme to complete in the weeks leading up to their surgery. Group 2 will continue to receive standard care only and document any activity that they usually perform

What are the possible benefits and risks of participating?
There may be no direct benefit to taking part in this study. There is the potential that prehabilitation can improve patient fitness and outcomes from cardiac surgery. The results of this study may benefit the future care of patients undergoing heart surgery.

Where is the study run from?
The James Cook University Hospital

When is the study starting and how long is it expected to run for?
October 2019 to April 2023

Who is funding the study?
1. Heart Research UK
2. National Institute for Health Research (NIHR)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
43139

Study information

Scientific Title
Prehabilitation in elective patients undergoing cardiac surgery: a randomised controlled trial

Acronym
PrEPS

Study objectives
Prehabilitation will improve pre-operative physical, functional and clinical outcomes in elective patients awaiting cardiac surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/10/2019, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)207 104 8086; nrescommittee.yorkandhumber-sheffield@nhs.net), ref: 19/YH/0317

Study design
Randomized; Interventional; Design type: Prevention, Process of Care, Physical, Rehabilitation, Other

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
Cardiac surgery

Interventions

Potentially eligible patients will be sequentially assigned a screening identification number irrespective of their participation in the trial and will be sent the participant information sheet (PIS) and a letter of invitation prior to attending their routine surgical clinic appointment. Patients expressing an interest in the trial will have the opportunity to ask questions and discuss the trial at this appointment.
Eligibility will be confirmed by the consultant surgeon at the time of listing for Surgery by completing an eligibility checklist before seeking written informed consent

A series of baseline assessments will be performed including the 6-minute walk test (6MWT), Maximal Inspiratory Pressure (MIP), quality of life questionnaires, Rockwood frailty score, handgrip strength, medical history, height, weight and demographics.

Randomisation:
Eligible patients will be randomised (allocated) to one of two groups and stratified by their baseline frailty scores. Half of the patients will receive prehabilitation and half will receive standard care only. Randomisation will be performed using a web-based system, managed by Newcastle Clinical Trials Unit which will be secure and prevent allocations being revealed until needed.

Intervention group:
Participants randomised to the prehabilitation group will be asked to attend hospital-based prehabilitation classes twice weekly for 4 weeks. An initial assessment will be carried out by a cardiac rehab physiotherapist at the first class. This assessment combined with the outcomes of the 6MWT will be used to develop a treatment programme tailored to the individual's abilities. Participants will also be advised on a tailored exercise programme to carry out at home over the 4 week period. Participants will be provided with a patient diary and asked to document any form of exercise and duration that they carry out independently as well as during the prehabilitation sessions.

Control group:
Participants randomised to the standard care group will be asked to continue with the advice provided by the clinical team. Participants will be provided with a 4-week patient diary and asked to document any form of exercise and duration that they carry out independently.

Assessments following intervention:
All participants attend a routine pre-assessment clinic 1-2 weeks prior to surgery to assess fitness for surgery. Preassessment staff will be notified of the patient's inclusion in the study. At this clinical appointment the research team will see the participant and complete the post-intervention assessments including the 6MWT, IMP, handgrip strength and patient-reported quality of life, HADS and satisfaction questionnaires. Patients will be asked about any adverse events that they have experienced from the time of randomisation. In the event that a patient is not seen by the research team at the time of this clinic, efforts will be made to obtain the study information once the patient has been admitted for surgery or a separate study visit if necessary. Patients will attend follow up visits at the hospital 6 weeks (routine care) and 12 weeks (study-specific) after their cardiac surgery to perform the 6MWT, MIP, handgrip strength, HADS and EQ5D5L.

Patients will complete the following assessments:
• 6MWT, MIP, handgrip strength, HADS and EQ5D5L at baseline, pre-operative assessment, 6 and 12 weeks post-op

• Patient exercise diary between randomisation and day of surgery
• Patient satisfaction questionnaire at the pre-operative assessment visit
• Adverse events from point of randomisation until day of surgery
All other information, including Euroscore II, complications (such as stroke), surgical outcomes, and data for longer-term follow-up over the full duration of the study, will be taken from medical records and other routinely collected data sources.

The trial will be overseen by a Trial Oversight Committee that will contain independent members and members of the TMG. The Trial Management Group may be made up of the CI, NCTU co-investigators, statistician, Senior Trial Manager and the Trial Manager as required.

Intervention Type
Other

Primary outcome measure
Change in exercise capacity measured by the 6-minute walk test (6MWT) from baseline to post-prehabilitation intervention (at 4-weeks and prior to surgery)

Secondary outcome measures
1. Exercise capacity is measured using the 6-minute walk test at 6 and 12 weeks following the index surgery exercise capacity following surgery
2. Respiratory function is assessed using Maximal Inspiratory Pressure (MIP)at baseline, at the pre-surgical assessment, and at 6 and 12 weeks following the index surgery
3. Patient-reported quality of life is assessed using the EQ-5D-5L at baseline, at the pre-surgical assessment and at 6 and 12 weeks following the index surgery
4. Handgrip strength is assessed as a measure of frailty using a dynamometer at baseline, at the pre-surgical assessment and at 6 and 12 weeks following the index surgery
5. Anxiety and depression is assessed using the Hospital Anxiety and Depression Scale (HADS) at baseline, at the pre-surgical assessment and at 6 and 12 weeks following the index surgery
6. Surgical and post-operative data (including duration of operation, cardiopulmonary bypass times, time on ICU and discharge information) will be collected from participants' medical notes and recorded on Case Report Forms (CRF) during their stay in hospital
7. Post-operative cardiac and pulmonary complications and hospital stay data will be collected, during the inpatient stay and at the 6 and 12 week follow up following the index surgery
8. Case Report Forms (CRF's) will capture data regarding the adherence and delivery of the intervention components from baseline to the day of surgery. Deviations from the proposed intervention components and timescales will be documented
9. Screening logs will be used to collect recruitment rate data including; the number of patients who meet the eligibility criteria, reasons for exclusion and for patients choosing not to participate in the study
10. CRF's will be used to capture the completion of research activity and protocol adherence at each of the data collection time points (baseline, pre-surgical assessment, point of surgery, 6 weeks and 12 weeks following the index surgery). Reasons for lack of attendance and withdrawal from study activity will be collected
(added 13/10/2022)
11. Patient reported activity from randomisation until surgery using an activity diary.

Overall study start date
01/05/2019

Completion date

30/04/2023

Eligibility

Key inclusion criteria
1. Patients listed for elective cardiac surgery at the James Cook University Hospital
2. Age > = 18 years
3. Ability to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 180; UK Sample Size: 180

Key exclusion criteria
1. Unstable angina/ indication for urgent surgery
2. Malignant arrhythmias
3. Pregnancy
4. Currently participating in another interventional clinical trial
5. Contraindications to cardiac prehabilitation:
5.1 Acute systemic illness or fever
5.2 Uncontrolled atrial or ventricular arrhythmias
5.3 Uncontrolled sinus tachycardia (HR> 120 bpm)
5.3 Acute pericarditis or myocarditis
5.4 Uncompensated HF
5.5 Third degree (complete) atrioventricular (AV) block without pacemaker
5.6 Recent embolism
5.7 Severe Musculoskeletal conditions that would prohibit exercise
6. Contraindications to inspiratory muscle training:
6.1 History of spontaneous pneumothorax/ incomplete recovery following traumatic pneumothorax
6.2 Asthma patients who suffer from frequent, severe exacerbations
6.3 Recently perforated ear drum (within last 3 months)
6.4 Large lung Bullae

Date of first enrolment
08/11/2019

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Cheriton House
Marton Road
Middlesbrough
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TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

Sponsor details
James Cook University Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Charity

Funder Name

Heart Research UK; Grant Codes: RG2671/18/20

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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/10/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/01/2023	09/01/2023	Yes	No
HRA research summary			28/06/2023	No	No