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Outcome monitoring after cardiac surgery

Submission date 22/10/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/01/2015	**Overall study status** Completed	
Last Edited 07/02/2025	**Condition category** Surgery	

Plain English summary of protocol

Current plain English summary as of 06/02/2019:
Background and study aims
After cardiac (heart) surgery, patients routinely have a follow-up appointment six weeks after discharge. After this appointment the patient is usually referred back to the care of their general practitioner (GP) and no longer receives care from, nor is followed up by, the cardiac surgery team. This study will involve patients being monitored in the long-term after cardiac surgery (for example, to find out how many patients experience major adverse cardiac events). These data will allow audit of cardiac surgery services and provide data to investigate risk factors for poor outcomes.

Who can participate?
Patients aged 18 or over who have had cardiac surgery at the Bristol Heart Institute.

What does the study involve?
We propose to collect consent from potential participants to access their data collected in NHS databases (used for clinical care) and from Hospital Episode Statistics (HES). We are particularly interested in outcomes such as stroke or heart attack that occur after surgery. Participants will be given a choice of participating electronically or via post. If participants choose to receive postal newsletters, it will be made clear that they are providing their consent to outsource sending an annual newsletter to a mailing company. We will also ask participants to complete a questionnaire relevant to the surgery they have received and/or a quality of life questionnaire at 3 months and 12 months after the surgery. There will also be a nested study to investigate whether the presentation style and format of the paper information leaflets provided to potential participants has an effect on the consent rates to the study. Participants will be randomly allocated to receive the information in three different formats, one of which is used routinely, the other two representing new styles. The content of each format will be the same. Participants will not be informed about this nested study.

What are the possible benefits and risks of participating?
The main benefit to society is the provision of high quality evidence to identify areas where research may benefit patient care and inform the design of such studies. Future patients and the NHS may benefit from such research. Participants may perceive a benefit from continued contact from the centre where they had their heart surgery. This is an observational study that will not change the participants' standard care. There are therefore no risks resulting from the

study to participant safety. The main risk is reminding participants of a time that was stressful and perhaps difficult for them; however, in our experience the majority of participants do appreciate the additional follow-up. There are no risks or anticipated benefits to participants as a result of the nested study.

Where is the study run from?
The study is run from the Clinical Trials and Evaluation Unit Bristol, University of Bristol, and based in the Bristol Heart Institute, University Hospitals Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2015 to March 2024

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

Who is the main contact?
Dr Lucy Culliford

Previous plain English summary:
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Study website
https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/omacs/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title
Outcome Monitoring After Cardiac Surgery: Cohort study with a nested randomised controlled trial

Acronym
OMACS

Study objectives
The aim of this study is to collect information about the medium- and long-term health status of patients who have had cardiac surgery. This will be used to inform the design of future studies, and to provide data for observational studies.
We are also preforming a nested RCT where we hypothesise that the format of information given to patients will affect participation rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Nottingham 2, 04/12/2014, ref: 2 21/10/2014

Study design
Single centre prospective cohort study with a nested randomised controlled trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Current interventions as of 06/02/2019:
The patient information leaflets (PILs) have the same text, and the text varies from 2 formats used as standard in our institution: A4 sheet with no colour and A5 booklet with no colour, the

'intervention' which is a colour printed tri-fold leaflet. The randomisation sequence will be generated by our statistical team, and the study database will randomised participants in a 1:1:1 ratio to each of the PIL formats. The study will then compare uptake rates for the study in each of the groups.

Blood samples will be collected from patients before, during and after surgery for use in other ethically approved studies.

Follow-up: patients will receive a QoL questionnaire at 3 months after their operation (with the PIL and consent form) and at 12 months, at which point active participation will cease and event data will be collected using Hospital Episode Statistics for 5 years.

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Intervention Type
Other

Primary outcome measure
Primary outcome for the Outcome Monitoring
1. MACE
2. Mortality data from the Personal Demographics Service.

Primary outcomes for the nested RCT: Participant uptake in the study for each format of the information leaflet

Secondary outcome measures
1. NHS resource use
2. Quality of life instruments - Coronary Revascularisation Outcome Questionnaire (CROQ) and /or short-form-12 (SF12) questionnaire
3. International normalised ratio (INR) values e.g. in participants having valve surgery or with persistent post-operative atrial fibrillation.

Overall study start date
03/12/2013

Completion date
26/03/2024

Eligibility

Key inclusion criteria

Patients, aged 18 years or above, who have had cardiac surgery at the Bristol Heart Institute.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1590 for the nested study

Total final enrolment
4069

Key exclusion criteria
1. Prisoners
2. Patients unable to give consent through mental incapacity
3. Patients whose main residence is outside the UK

Date of first enrolment
03/06/2016

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Trials and Evaluation Unit Bristol
School of Clinical Sciences
University of Bristol
Level 7 Queens Building
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
R&I Department
Level 3, UH Bristol Education Centre
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) Cardiovascular BRU (UK)

Results and Publications

Publication and dissemination plan
1. Planned publication of the results of the nested study in peer reviewed journals
2. Production of an annual newsletter to disseminate information to participants

Intention to publish date
31/12/2024

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

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Nested study results	27/12/2019	31/12/2019	Yes	No
Protocol article		19/12/2022	20/12/2022	Yes	No
Other unpublished results			11/07/2024	No	No
Basic results			15/07/2024	No	No
Results article	Cohort profile	05/02/2025	07/02/2025	Yes	No