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Conventional versus minimally invasive extra-corporeal circulation in patients undergoing cardiac surgery: a randomised controlled trial

Submission date
18/12/2017

Recruitment status
No longer recruiting

Registration date
18/01/2018

Overall study status
Completed

Last Edited
29/02/2024

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
Miniaturised heart-lung machines (minimally invasive extracorporeal circulation; MiECC) have been developed with the aim of reducing the number of post-operative complications arising from using conventional heart-lung machines (CECC). Due to the variety of miniaturised systems that have been evaluated, the different types of patients and outcomes investigated, and the poor quality of previous studies, the effectiveness of MiECC in reducing post-operative complications has not been established and most hospitals continue to use CECC. Compared to CECC, using MiECC during cardiac surgery may reduce the proportion of patients having one of several serious postoperative complications (death, heart attack, stroke, gut infarction, severe acute kidney injury, reintubation, tracheostomy, mechanical ventilation for more than 48 hours, or reoperation). In addition, MiECC may reduce the amount of blood products transfused, time to discharge from the cardiac intensive care unit and hospital and the health care resources used during the hospital stay. The aim of this study is to evaluate the MiECC system and to detect if there is a reduction in risks as compared to the CECC.

Who can participate?
Adults aged 18 to 85 who are undergoing any elective or urgent coronary artery bypass surgery, aortic valve replacement or both using a heart-lung machine without circulatory arrest.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group undergo surgery using the MiECC system. Those in the second group undergo surgery using CECC. Participants are followed up twice, at 30 days and at 90 days after surgery to look at the serious adverse events and their health quality of life.

What are the possible benefits and risks of participating?
The risks of having cardiac surgery are different from person to person, depending on the severity of heart disease, type of operation, age, and current state of health. Both types of heart and lung machines are used currently for heart operations in the NHS. At present, hospitals can choose either machine as there is little evidence to decide which machine is better.

Where is the study run from?
1. Bristol Royal Infirmary (UK)
2. Derriford Hospital (UK)
3. Hammersmith Hospital (UK)
4. Castle Hill Hospital (UK)
5. Royal Papworth Hospital (UK)
6. Aristotle University of Thessaloniki (Greece)
7. Inselspital, Universitätsspital Bern (Switzerland)
8. Universitätsklinikum Ulm (Germany)
9. Klinikum Braunschweig (Germany)
10. Ankara Numune Egitim Arastirma Hastanesi (Turkey)
11. Saud Al Babtain Cardiac Center (Saudi Arabia)

When is the study starting and how long is it expected to run for?
January 2017 to December 2020

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

Who is the main contact?
Mr Jonathan Evans (Scientific), comics-trial@bristol.ac.uk
Professor Gianni Angelini – Chief Investigator
Professor Kyriakos Anastasiadis – Principal Investigator, Lead for EU-Countries
Professor Thierry Carrel – Principal Investigator, Lead for Non-EU Countries

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 36468

Study information

Scientific Title
Conventional versus Minimally Invasive extra-corporeal circulation in patients undergoing Cardiac Surgery: a randomised controlled trial

Acronym
COMICS

Study objectives

The primary hypothesis is that, compared to CECC, using MiECC during cardiac surgery reduces the proportion of patients experiencing post-operative morbidity.

The proposed trial will overcome most limitations of previous trials of MiECC. It will: (a) evaluate MiECC system that meet specified criteria which are used in participating centres; (b) be large enough to influence clinical practice, since it will be able to detect a worthwhile benefit in an outcome relevant to patients, surgeons and health services; (c) include a range of features to prevent bias.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Central Bristol Research Ethics Committee, 29/11/2017

Study design
Randomized; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
The patient information sheet can be made available on request email: comics-trial@bristol.ac.uk

Health condition(s) or problem(s) studied
Cardiac surgery

Interventions
This study is a multi-centre, two-group parallel randomised controlled trial to investigate the effects of using MiECC in all patients having elective or urgent coronary artery bypass grafting (CABG), aortic valve replacement (AVR) or CABG+AVR using extra-corporeal circulation without circulatory arrest. The research objectives are addressed by randomising participants (1:1 ratio) to have surgery using MiECC system or CECC.

Patients undergoing any elective or urgent CABG, AVR, or CABG+AVR, with extra-corporeal circulation and without circulatory arrest are invited to participate. Potential trial participants are identified from operating lists. All potential participants are sent or given an invitation letter and a PIL describing the study.

Randomisation take place as close to surgery as possible and is performed by an authorised member of the local research team not involved in post-operative data collection. Participants and members of the local research team responsible for data collection are blind to the allocation.

The intervention is applied only for the duration of extra-corporeal circulation without circulatory arrest.

Participants are followed up twice, at 30 days and 90 days after surgery: questions elicit information about SAEs experienced since discharge (including readmissions) at 30 days and HRQoL (using the EQ-5D-5L) will be assessed at both times.

Intervention Type
Other

Primary outcome measure
Composite of post-operative serious adverse events (SAEs) are measured using questions to patients during hospital stay and at 30 days post randomisation via a postal or telephone questionnaire. All SAEs that qualify for the primary outcome will be objectively defined and validated. The following events will qualify:
1. Death
2. Myocardial infarction (MI; suspected events will be documented by serum troponin concentrations and electrocardiograph recording (ECG) and adjudicated)
3. Stroke (report of brain imaging (CT or MRI), in association with new onset focal or generalised neurological deficit)
4. Gut infarction (diagnosed by laparotomy or post mortem)
5. AKI Network criteria for stage 3 AKI [16]
6. Reintubation
7. Tracheostomy
8. Mechanical ventilation for >48 hours, including multiple episodes when separated by more than 12 hours
9. Reoperation
10. Percutaneous intervention
11. Sternal wound infection with dehiscence
12. Septicaemia confirmed by microbiology

Secondary outcome measures
1. All-cause mortality is measured using questionnaires 30 days after randomisation
2. Other SAEs are measured using questionnaires 30 days after randomisation
3. Units of RBC transfused up to 30 days after randomisation
4. Other blood products transfused up to 30 days after randomisation
5. Time to discharge from cardiac ICU is measured using patient notes during the index admission
6. Time to discharge from hospital is measured using patient notes following the index admission
7. Delirium in ICU, assessed with the Intensive Care Delirium Screening Checklist (ICDSC) [17] for up to 5 days; this outcome will only be collected in a subset of participating hospitals that have the capability to do so.
8. Health related quality of life is measured using the HRQoL using the EQ-5D-5L [18] up to 90 days after randomisation; responses to this instrument can be mapped on to ‘valuations’ for the economic evaluation

9. Health and social care resources and associated costs up to 90 days after randomisation are measured using the patient in hospital stay and again at 30 and 90 days post randomisation via a postal or telephone questionnaire

Overall study start date
18/01/2017

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Age ≥18 and <85 years
2. Undergoing any elective or urgent CABG, AVR surgery, or CABG+AVR surgery, using extra-corporeal circulation without circulatory arrest

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
Planned Sample Size: 3500; UK Sample Size: 650

Total final enrolment
1071

Key exclusion criteria
1. Requirement for emergency or salvage operation
2. Requirement for major aortic surgery (e.g. aortic root replacement)
3. Contraindication or objection (e.g. Jehovah's Witnesses) to transfusion of blood products
4. Congenital or acquired platelet, red cell or clotting disorders (patients with iron deficient anaemia will not be excluded)
5. Inability to give informed consent for the study (e.g. learning or language difficulties)

Date of first enrolment
05/02/2018

Date of final enrolment

01/12/2020

Locations

Countries of recruitment
England

Germany

Greece

Saudi Arabia

Switzerland

Türkiye

United Kingdom

Study participating centre
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Study participating centre
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University of Bristol

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name

British Heart Foundation (BHF)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The protocol can be made available on request email: comics-trial@bristol.ac.uk

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
At the end of the study, once analysed, anonymised datasets generated during the study can be available on request, please contact bristol-cteu@bristol.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/08/2020	27/02/2023	Yes	No
Protocol file	version 3.0		20/07/2023	No	No
Plain English results			21/07/2023	No	Yes
Basic results		29/02/2024	29/02/2024	No	No