ISRCTN11514932 https://doi.org/10.1186/ISRCTN11514932

Comparing blood cell damage in two types of heart-lung machines in patients undergoing open-heart surgery

Submission date
18/11/2020

Recruitment status
No longer recruiting

Registration date
09/12/2020

Overall study status
Completed

Last Edited
09/07/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Coronary artery bypass grafting (CABG) is a type of heart surgery used to treat coronary heart disease. It diverts blood around narrowed or clogged parts of the major arteries to improve blood flow and oxygen supply to the heart.
During heart surgery, the vital functions are maintained by a heart-lung machine. Heart-lung machines are known to cause blood cell damage. The aim of this study was to compare the amount of blood cell damage caused by two different types of heart-lung machines. Both heart-lung machines are used on a daily basis. This study will support future decision making of which type of heart-lung machine should be used during an operation.

Who can participate?
Patients scheduled to undergo coronary artery bypass grafting (CABG) surgery.

What does the study involve?
Participants were randomly allocated to one of two types of heart-lung machine. Blood samples were taken at 6 points in time after the induction of anesthesia. Per patient a total of 72 mL blood was collected through the central line or from the heart-lung machine and patients did not undergo extra interventions for this study.

What are the possible benefits and risks of participating?
For each individual patient no benefits or risks were involved by performing this study.

Where is the study run from?
Amphia Hospital in Breda (Netherlands)

When is the study starting and how long is it expected to run for?
September 2016 to May 2018

Who is funding the study?
1. Amphia Hospital (Netherlands)
2. Sanquin Amsterdam (Netherlands)

Who is the main contact?
Denise Hoogzaad, dhoogzaad@amphia.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL59160.015.16

Study information

Scientific Title
Hemolysis and cell death in conventional versus miniaturized cardiopulmonary bypass systems

Acronym
ECCiH study

Study objectives
The MiECC system induces less hemolysis and cell death than the CECC system

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/01/2017, Medisch ethische toetsingscommissie Maxima medisch centrum (De Run 4600, 5504 DB Veldhoven, Netherlands; +31 (040) 888 95 28; metc@mmc.nl), ref: W16.122

Study design
Single-center prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files (in Dutch)

Health condition(s) or problem(s) studied
Patients undergoing coronary artery bypass grafting with cardiopulmonary bypass

Interventions
Patients that required planned CABG surgery were randomly assigned for inclusion in one of two groups: (1) patients maintained by Conventional extracorporeal circulation system (n=20), (2) patients maintained by MiECC (n=20).

Samples were collected in the operation theater and in the ICU. In the ICU, samples were collected 2,5-3 hours after weaning from ECC and administration of protamine. There was no further follow-up for the included patients. We used the program Castor for the randomization process.

Intervention Type
Procedure/Surgery

Primary outcome measure
Hemolysis was measured using free Hb and LDH as parameters. Blood was obtained at baseline, at 5 and 30 min, 10 min after clamp removal, post ECC and post-surgery at the intensive care unit (ICU)

Secondary outcome measures
Cell death and neutrophil activation were measured using nucleosome and HNE-a1-ATc ELISA's. Blood was obtained at baseline, at 5 and 30 min, 10 min after clamp removal, post ECC and post-surgery at the intensive care unit (ICU)

Overall study start date
01/09/2016

Completion date
11/05/2018

Eligibility

Key inclusion criteria
1. Elective isolated CABG surgery with CPB at Amphia hospital
2. Male or female ≥18 years
3. The graft material used could be the: left internal mammary artery (LIMA), Right internal mammary artery (RIMA), Saphenous vein or Radial artery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. The creatinine level >150µmol/L
2. Aspartate transaminase (ASAT) level >80 U/L
3. Ejection Fraction (EF) <30%
4. BSA <1.6, ≥2.5m²
5. Carotid artery stenosis
6. Hemoglobin level <7.5, ≥10 mmol/L
7. Pre-operative red blood cell transfusion, <14 days before CABG procedure

Date of first enrolment
19/09/2017

Date of final enrolment
15/03/2018

Locations

Countries of recruitment

Netherlands

Study participating centre
Amphia hospital
Molengracht 21
Breda
Netherlands
4818CK

Sponsor information

Organisation
Amphia Ziekenhuis

Sponsor details
Molengracht 21
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Sponsor type
Hospital/treatment centre

Website
http://www.amphia.nl/Pages/default.aspx

ROR
https://ror.org/01g21pa45

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Amphia Hospital

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/01/2021	No	Yes