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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
18/11/2020		Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/12/2020 Last Edited	Completed Condition category	☐ Results		
		Individual participant data		
09/07/2021	Surgery	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. Sanguin Amsterdam (Netherlands)

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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s))

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Sponsor information

Organisation

Amphia Ziekenhuis

ROR

https://ror.org/01g21pa45

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Amphia Hospital

Funder Name

Sanquin Amsterdam

Results and Publications

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		Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes