# 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	Completed	Results		
Last Edited	Condition category	[] 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

Ms Denise Hoogzaad

#### **ORCID ID**

http://orcid.org/0000-0003-2264-4352

#### Contact details

Molengracht 21 Breda Netherlands 48181CK +31 (0)765955126 dhoogzaad@amphia.nl

# 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, ≥2.5m<sup>2</sup>
- 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

## Study participating centre Amphia hospital

Molengracht 21 Breda Netherlands 4818CK

# Sponsor information

## Organisation

Amphia Ziekenhuis

## Sponsor details

Molengracht 21 Breda Netherlands 4818CK +31 (0)76 595 1508 BGerritse@amphia.nl

## 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