

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

<b>Submission date</b> 18/11/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/07/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

### Contact name

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## Additional identifiers

### 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  $\geq 18$  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  $>150\mu\text{mol/L}$
2. Aspartate transaminase (ASAT) level  $>80\text{ U/L}$
3. Ejection Fraction (EF)  $<30\%$
4. BSA  $<1.6, \geq 2.5\text{m}^2$
5. Carotid artery stenosis
6. Hemoglobin level  $<7.5, \geq 10\text{ mmol/L}$
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

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?
<a href="#">Participant information sheet</a>			04/01/2021	No	Yes