Pilot study: A comparison of the extent of haemolysis induced by conventional versus miniaturised extracorporeal circulation during coronary artery bypass grafting surgery, and the influence on the release of damage associated molecular patterns (DAMPs), leukocyte activation and neutrophil extracellular trap (NET) formation.

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Primary Objective: To compare the extent of haemolysis associated with the use of the conventional versus the miniaturised heart lung machine in the Amphia hospital, with the aim to set up evidence-based guidelines for the use of a specific type of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haemolyses and related conditions
Study type	Observational invasive

Summary

ID

NL-OMON45709

Source
ToetsingOnline

Brief title
Extent and effect of haemolysis induced by extracorporeal circulation

Condition

- Haemolyses and related conditions
- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
cell dead of red blood cells, haemolysis

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Amphia hospital en Sanquin research

Intervention

Keyword: CABG, ECC, Haemolysis, Neutrophils

Outcome measures

Primary outcome

The main study parameter is the amount of haemolysis as examined by determining cell free haem/cell free haemoglobin, haemoglobin, haematocrit and lactate dehydrogenase.

Secondary outcome

Secondary study parameters are markers for the release of DAMPs (nucleosomes, cell free DNA HMGB1), the activation of leukocytes (calprotectin) and neutrophils (human neutrophil elastase-alpha1 antitrypsin complexes) and the formation of neutrophil extracellular traps (myeloperoxidase(MPO)-nucleosome complexes).

Study description

Background summary

Each year approximately eight thousand patients in the Netherlands undergo coronary artery bypass grafting (CABG) surgery. . In the majority of cases a heart-lung machine (HLM) is used for extracorporeal circulation (ECC). Two different types of heart-lung machine set-ups are currently in use for CABG surgery in the Amphia hospital; the conventional HLM and a miniaturised HLM. It is known that contact of blood with the components of the HLM induces haemolysis. We aim to collect data on the extent of haemolysis induced by each type of HLM, as such information may be used for a more evidence based decision in the use of a specific HLM and will potentially improve patient outcome. Secondly, this study will focus on the release of damage associated molecular patterns (DAMPs), leukocyte activation and neutrophil extracellular trap (NET) formation induced by ECC. Leukocytes, including neutrophils, may be directly activated after contact with the HLM, or as a consequence of the released haemolytic breakdown products and the associated tissue damage. Since the HLM is known to cause significant haemolysis during ECC, we will look for possible correlations between haemolysis and the release of DAMPs, leukocyte activation markers and markers of NET formation in patients undergoing CABG surgery.

Study objective

Primary Objective: To compare the extent of haemolysis associated with the use of the conventional versus the miniaturised heart lung machine in the Amphia hospital, with the aim to set up evidence-based guidelines for the use of a specific type of heart-lung machine in CABG surgery.
Secondary Objectives: (1) To explore the extent of DAMPs release, leukocyte activation and neutrophil extracellular trap release in patients undergoing CABG surgery with extracorporeal circulation. (2) To determine whether direct correlations exist between the extents of haemolysis on the one hand, and DAMPs release, leukocyte activation and neutrophil extracellular trap release on the other hand, in the context of the use of two types of heart-lung machines in patients undergoing CABG surgery.

Study design

Prospective randomized cohort study.

Study burden and risks

A total of 72ml blood will be collected at six time point from patients undergoing coronary artery bypass grafting procedures. There is at present no evidence to suggest that participation in the study holds additional risk.

Patients are not positively or negatively affected when participating in this study. No additional venepuncture is needed for blood collections.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Elective CABG operation with extracorporeal circulation

Exclusion criteria

o Kidney insufficiency: creatinine >150 µmol/L
o Liver insufficiency: ASAT >80 U/L

o Left ventricular function (LVF): <30% Ejection fraction (EF)
o Body surface area (BSA): <1.6; *2.1 m²
o Carotid artery stenosis
o Pre-operative Haemoglobin: <7,5; *10 mmol/L
o Pre-operative red blood cell transfusion: <14 days before CABG procedure
o Splenectomy (influences the IgM levels used to determine the amount of haemodilution)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL59160.015.16