ISRCTN17452821 https://doi.org/10.1186/ISRCTN17452821

Can a method called "goal-directed perfusion" help reduce damage to blood cells and swelling during heart surgery using a cardiopulmonary bypass machine? Comparison with the conventional method

Submission date 27/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/04/2023	**Overall study status** Completed	
Last Edited 26/09/2023	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

During heart surgery, the use of a heart-lung machine (cardiopulmonary bypass; CPB) can cause problems like damaged red blood cells, an inflammatory response in the whole body, blood clotting, and activation of white blood cells. These problems can lead to bad results. Researchers think that using a method called goal-directed perfusion during heart surgery with the heart-lung machine may lower the chances of these problems. This study wants to see if using goal-directed perfusion during heart surgery with the heart-lung machine can cause less damage to red blood cells and inflammation compared to the usual way of doing it.

Who can participate?

Cardiac surgery patients requiring CPB, between 18-65 years of age.

What does the study involve?

Patients will receive one of two CPB procedures, i.e. goal-directed perfusion and conventional perfusion methods. other than that, all patients will receive similar treatments.

What are the possible benefits and risks of participating?

Possible benefits of GDP methods are reduced risk of SIRS and hemolysis, reduced length of stay, and better outcomes, while the potential risks are inadequate blood delivery from CPB machine

Where is the study run from?

Universitas Gadjah Mada, Yogyakarta, Indonesia

When is the study starting and how long is it expected to run for?

August 2022 to October 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Bhirowo Yudo Pratomo, bhirowo@ugm.ac.id

Contact information

Type(s)
Principal investigator

Contact name
Dr Bhirowo Pratomo

ORCID ID
https://orcid.org/0000-0002-0815-5440

Contact details
Jalan Kesehatan no 1
Yogyakarta
Indonesia
55284
+62-8122655243
bhirowo@ugm.ac.id

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The comparison between goal-directed perfusion vs conventional method in cardiopulmonary pulmonary bypass: effects on hemolysis and inflammation

Study objectives
Cardiopulmonary bypass (CPB) with Goal-Directed Perfusion may reduce the incidence of hemolysis and inflammation compared with conventional method

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/02/2023, Medical and Health Research Ethics Committee of Universitas Gadjah Mada (Jl Kesehatan no 1, Sekip, Yogyakarta, Indonesia; +(62)274 588688; mhrec_fmugm@ugm.ac.id), ref: KE/FK/0232/EC/2023

Study design
Single center double blind randomized clinical trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cardiac surgery patients who require cardiopulmonary bypass procedure

Interventions
The study will use a double-blind randomized clinical trial design to investigate the effects of goal-directed perfusion using the heart-lung machine on hemolysis and inflammation in adult patients undergoing heart surgery. Patient will be informed consent before the randomization to get the detail of the surgery and its intervention. The randomization will be done with computerized permutation block randomization, and each participant will be obtaining random numbers and assigned to chosen treatment condition. Additionally, those who perform the randomization will not be involved in the study either as operators or data collectors. The CPB machine operator or perfusionist will only carry out the procedure according to the allocation of the randomization sample, and the laboratory examiners will be blind to the treatment condition assigned to each participant.

The population for this study will be adult heart surgery patients who undergo heart surgery at the RSUP Dr. Sardjito Yogyakarta using the heart-lung machine and meet the strict inclusion and exclusion criteria. The study will start in May 2023 and will continue until the desired sample size is achieved. The inclusion criteria for the study are adult heart surgery patients who use the heart-lung machine for valve replacement or repair surgery or coronary artery bypass, aged 18-65 years, with NYHA (New York Heart Association) class I or II, a body weight of 40-100 kg. The exclusion criteria are patients who use extra-corporeal circulation before surgery (such as IABP, hemodialysis, renal replacement continuous therapy, or intraventricular assisted device), have a history of severe hemolysis and inflammation, and require emergency or urgent heart surgery. Patients with any unstable comorbidities, such as liver disease, renal failure, or heart failure, will also be excluded. Additionally, patients who have a history of receiving blood transfusions within three months before surgery, those who are pregnant, and those who are not able to provide informed consent will be excluded from the study. The drop-out criteria are heart surgery lasting less than 60 minutes using the heart-lung machine or patient death before heart-lung machine use.

All heart surgeries will use a Sorin type C5 CPB machine with oxygenator Terumo Capiox FX 15 RW 20 or Capiox FX 15 RW 25. The heart surgery team will consist of two cardiac surgeons with the same level of competency and experience, one performing surgery for structural heart abnormalities and the other surgeon performing CABG surgery, assisted by two cardiovascular

anesthesiologist and two perfusionists with the same level of competency and experience. Sample collection will begin on May 1st, 2023, and data collection will occur simultaneously until approximately August 15th, 2023, or the last cardiac surgery patient is discharged from the ICU.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Hemolysis markers
1.1. Plasma free hemoglobin is measured with colorimetric hemoglobin assay, at baseline, 60, 90, and 120 min during CPB
1.2. Haptoglobin is measured with ELISA method, at baseline, 60, 90, and 120 min during CPB
2. Inflammatory markers
2.1. Interleukin – 6 is measured with ELISA method, at baseline, 60, 90, and 120 min during CPB
2.2. TNF-α is measured with ELISA method, at baseline, 60, 90, and 120 min during CPB

Key secondary outcome(s))
1. Complete blood count, peripheral blood morphology, blood glucose, electrolytes, urea and creatinine, lactate, arterial blood glass are measured in accordance with lab protocols, at baseline, 60, 90, and 120 min during CPB
2. Duration of postoperative ventilator use, ICU length of stay are measured as hours and days, respectively

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Cardiac surgery patients that require CPB procedures
2. New York Heart Association (NYHA) < 3
3. Body weight 40 - 100 kg

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients under extra corporeal circulation before surgery: IABP, hemodialysis, RRT, intraventricular assisted device

Date of first enrolment

01/07/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
Indonesia

Study participating centre
Dr Sardjito General Hospital
Jl. Kesehatan no. 1
Yogyakarta
Indonesia
55284

Sponsor information

Organisation
Gadjah Mada University

ROR
https://ror.org/03ke6d638

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Department of Anesthesiology and Intensive Care, Faculty of Medicine, Nursing, and Public Health, Universitas Gadjah Mada.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/03/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			30/03/2023	No	No