INFORMED CONSENT

I, Dr. ..... (research team member), led by Dr. Bhirowo Yudo Pratomo, Sp. An, KAKV from the Department of Anesthesiology and Intensive Therapy, Faculty of Medicine, Public Health, and Nursing, Gadjah Mada University/Dr. Sardjito Hospital, will conduct a research entitled "COMPARISON OF GOAL DIRECTED PERFUSION HEART-LUNG BYPASS MACHINE WITH CONVENTIONAL METHOD: Impacts on Hemolysis, Inflammatory Response, and Tissue Metabolism". The research team invites you to participate in this study. This study requires approximately 50 patients who will undergo heart surgery using the heart-lung bypass machine and will be divided into two groups: one with conventional method and the other with GDP method.

Voluntary Participation in the Study

Participation in this study is voluntary. If you decide to participate, you are free to withdraw at any time without penalty or sanction. If you decline to participate, you will still undergo the standard heart surgery procedure, anesthesia, and care at Dr. Sardjito Hospital.

If you agree to participate in this study, you will be asked to sign the consent form in duplicate, one for you to keep and one for the researcher. The next procedure is as follows:

1. The study will be conducted in the Integrated Heart Center Operating Room (PJT) at Dr. Sardjito General Hospital in Yogyakarta. You will be explained about the anesthesia procedure by the staff and asked to sign the consent form.
2. The study will be conducted after obtaining approval from the Research Ethics Committee of the Faculty of Medicine, Public Health, and Nursing, Gadjah Mada University/Dr. Sardjito General Hospital.
3. If you have already registered for heart surgery at the PJT at Dr. Sardjito General Hospital in Yogyakarta, you will be interviewed by a doctor to ask for your name, age, current medical history, past medical history, previous anesthesia history, as well as weight and height data.
4. You will undergo a physical examination by a doctor to check your health status.
5. You will be given an explanation about the anesthesia procedure that will be performed, and if you agree, you will be asked to sign the consent form and advised to fast for 6 hours before the operation.
6. You will be prepared according to the general heart surgery procedure, undergo routine laboratory tests for pre-operation.
7. You will then undergo general anesthesia according to standard operating and anesthesia protocols and monitoring for heart surgery according to your clinical condition and health status.
8. During the operation, data will be recorded regarding the duration of the use of the cardiopulmonary bypass machine and the duration of the aortic cross-clamp.

9. Before and during the cardiopulmonary bypass machine, blood will be taken for examination as much as 3x5cc, which is useful to determine the inflammatory and blood damage conditions that occur during heart surgery due to the use of the cardiopulmonary bypass machine.
10. After the operation, you will be transferred to the postoperative cardiac intensive care unit (ICU) under the influence of anesthesia drugs. Intensive care will be given according to your clinical needs as long as you require strict monitoring during the postoperative period.
11. In the ICU; blood, EKG, urine, chest X-ray, and echocardiography examinations will be performed if necessary, according to the standard postoperative examination at Dr. Sardjito General Hospital.
12. The duration of the use of respiratory aids and the duration of care in the postoperative cardiac intensive care unit will be calculated.

Participant Obligations in Research

If you are willing to participate in this research, you are obligated to follow the instructions and procedures of the research as stated above. If there are any unclear points, you can ask the research team for further clarification.

Risks, Side Effects and Handling

This research is conducted under strict monitoring of physiological functions with standard cardiac surgery procedures at RSUP Dr. Sardjito. The aim of this research is to evaluate the process of inflammation and blood damage caused by the use of a heart-lung bypass machine during heart surgery. Researchers and the research team do not expect any risks or side effects during the data collection period of the research.

Benefits

The benefit of participating in this research is that you will receive strict monitoring and evaluation of the process of inflammation and blood damage caused by the use of a heart-lung bypass machine. This will enable proper treatment if deemed necessary.

Confidentiality

All information about your identity and clinical information will be kept confidential and only known by the researchers, research staff, and auditors. The research results will be published without identifying you as the respondent.

Compensation

You will not receive any compensation for your participation in this research.

Funding

All expenses related to this research will be borne by the researchers. Expenses arising from routine operation funding will be borne by the patient (guarantor) in accordance with the applicable rules at RSUP Dr. Sardjito.

Additional Information

You will be given the opportunity to ask any questions related to this research that are still unclear. If any unexpected events occur or further information is needed, you can contact Dr. Bhirowo Yudo Pratomo Sp. An, KAKV, at 081903736126. You can also inquire about this research from the Medical and Health Research Ethics Committee of the Faculty of Medicine, Public Health, and Nursing, Gadjah Mada University/RSUP Dr. Sardjito via email at mhrec_fmugm@ugm.ac.id.

LETTER OF AGREEMENT

All of the above explanations have been conveyed to me and all of my questions have been answered by the research team/doctor. I understand that if I need further information, I can ask Dr. Bhirowo Yudo Pratomo Sp. An, KAKV. I understand that I can refuse or withdraw from participation at any time without being fined or suffering any loss, and without having to give a reason for my decision.

By signing this form, I agree to participate in this research.

Patient's signature: Date:

(Full Name: …….)

Doctor's signature: Date:

(Full Name: …….)

Please include a "witness statement" if the patient/subject is unable to read this information document. A neutral witness must be present during the discussion of the research explanation.

Witness statement:

I, the undersigned, declare that the subject who has signed or provided a thumbprint on this research consent form has been explained in a language that is understood and has clearly understood about the research, risks, and benefits of their participation in this study.

(Full Name: …….)