The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Does Plasma Volume Replacement with 5% Human Albumin Reduce Endothelial Injury and Glycocalyceal Disruption compared with 6% Hydroxyethylstarch (130/0.4) in Patients having Cardiac Surgery? A substudy of the SHARP clinical trial
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After hours phone contact #: 216-444-2200

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study.**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research.**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**

This research study has been approved by the Institutional Review Board (IRB). The IRB is a committee that reviews human research studies to ensure the safety and welfare of research volunteers are protected in accordance with federal human subject regulations and ethical principles.

Why is the research study being done?

You are being invited to take part in this research study because you are participating in a study (Main Study) to evaluate the safety of a standard fluid replacement called 6% Hydroxyethylstarch 130/0.4 during surgery on kidney function. During the study you may receive one of two possible fluid replacements during surgery, if your fluid volume decreases enough to need replacement with one of the colloid fluids. These two possible fluid replacements are 6% Hydroxyethylstarch 130/0.4, a starch-containing fluid or 5% human albumin.

Endothelial dysfunction, which is the inability of arteries and arterioles to dilate fully are common following cardiac surgery. This study is being done to compare the reduction of endothelial dysfunction between 5% human albumin and 6% Hydroxyethylstarch 130/0.04.

How Many People Will Take Part In The Study?

About 85 patients will take part in this study at the Cleveland Clinic.

What is involved if you decide to take part in this research study?

If you decide to take part in this study, the blood samples that have been taken for the Main Study will also be used to measure the plasma concentrations of two biomarkers that measure endothelial injury.

However, within two hours of your arrival to the ICU peripheral arterial tonometry will be performed. A finger probe will be placed on each hand to record your arterial pulse. This pulse will be recorded for 5 minutes. Then a blood pressure cuff will be inflated on one arm. The pulse will be recorded for another 5 minutes, followed by cuff deflation and measurement for another 5 minutes (total of 15 minutes)

What are the alternatives to participation in the research study?

You do not have to take part in this research study to receive treatment at this hospital. This is a research study and you do not have to volunteer.

What are the risks of participating in the research study?

The EndoPat may cause some discomfort during the blood pressure inflation, which may feel similar to a limb "falling asleep". You may also notice a "tingly" feeling when the blood pressure cuff is released. These sensations will resolve completely within a few minutes after the completion of the test.

What are possible benefits of participating in the research?

There is no direct benefit to you from participation in this study. Knowledge gained from this research may help us determine if 5% human albumin or 6% Hydroxyethylstarch 130/0.04 reduces endothelial dysfunction more after cardiac surgery.

Are there any costs to you if you participate in this study?

There are no additional costs to you for participation in this research study. The cost for routine tests and services that would normally be performed even if you do not participate in the study will be billed to you or your insurance provider.

Are there any payments to you if you participate in this study?

You will not be compensated for your participation in this study.

What will happen if you are injured as a result of taking part in the research?

In the event you are injured as a result of participation in this research, medical care is available to you. The cost of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland

Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form.

Further information about research related injury is available by contacting the institutional review board at 216-444-2924.

What will happen to your information that is collected for this research?

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to Marta Kelava, M.D. and the research staff at Cleveland Clinic for the purposes of this research. Any information obtained in connection with this research study that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except required by law.

All participants will be given a study code number. All information about you that is collected for the study will be labeled with this number, not your name or hospital number. The key to the code will be stored separately to your information.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth and information from your medical records.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board and governmental agencies.

Records are collected and stored either in folders (for paper records) or put onto a secure computer, which can only be accessed by the researchers. All written data will be stored in a locked filing cabinet in a locked room. Only the researchers will have access to stored written or electronic data. Information collected from participants will be kept for 15 years after which it will be destroyed.

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

You may stop the uses and disclosures of your information at any time by writing to Marta Kelava, M.D. Cleveland Clinic 9500 Euclid Ave., E-30R Cleveland, Ohio 44195 (216-213-3218). Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, any information already disclosed outside the Cleveland Clinic cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic will not use your information collected in this study for another research purpose without your written permission unless the Cleveland Clinic Institutional Review Board

(IRB) assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research study will be recorded in your health records.

You have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Contact the study team member named at the end of this document if you would like to access your information.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

Who do you call if you have any questions or problems?

If you have any questions, you can ask the Principal Investigator and/or research staff.
Marta Kelava, M.D. at 216-213-3218.

If you are a Cleveland Clinic patient, you should contact the page operator at 216-444-2200 and ask to page 80756.

If you have any questions about your rights as a research subject, you may contact the Institutional Review Board (IRB) at Cleveland Clinic IRB 216-444-2924.

What are your rights as a research participant?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any time.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Cleveland Clinic.

In the event new information becomes available, that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

□ Please check this box if you agree to two additional EndoPAT exams. First one would be performed prior to your surgery after your preoperative assessment with an anesthesiologist. The second additional EndoPAT exam would be performed 24 (± 2) hours after your surgery.

Participation in additional measurements is optional. While you will likely be sedated for EndoPAT exam within 2 hours after your arrival to ICU, you will likely be awake for both additional measurements. Please refer to the information on the top of page 2 of this document for detailed description of the EndoPAT exam.

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date