

Cover Page for ClinicalTrials.gov

Document:
Informed Consent Form

Official Study Title:
Reducing Red Blood Cell Transfusion Requirements for Adults
Undergoing Surgical Resection of the Liver – A Quality Improvement Project

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Informed Consent Form (ICF) for Observational and/or Sampling/Testing Prospective Research with Human Participants (non-regulated) - HSREB

Study title: Reducing red blood cell transfusion requirement for hepatectomy – a quality improvement study.

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2. Introduction

You are being invited to participate in a research study because you are scheduled for a liver surgery which often requires a transfusion. This form provides information to help you make an informed decision about whether to participate. Please read this document carefully and ask any questions you may have. You are encouraged to discuss your participation with friends, family, or other healthcare providers. All your questions should be answered before you decide to participate in this research study. This study has received ethical approval from the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

Participation is voluntary, and you can decline to participate in any part of this research with no impact on your current or future medical care or your option to participate in future research. You can also change your mind at any time. Whatever choice you make you will not give up any legal rights or benefits.

3. Conflict of interest

There are no conflicts of interest to declare related to this study.

4. Purpose of study

A previous study has shown that removing a up to 10% of a patient's blood at the beginning of liver surgery and then putting it back near the end of surgery (called hypovolemic phlebotomy or HP for short) reduces the need for a blood transfusion by >38%. The purpose of this study is to implement HP at KGH to reduce the need for transfusion and reduce associated complications in patients undergoing liver surgery.

5. Who will take part in this study?

About 60 liver surgery patients will participate in this study. If you choose to do so, your time commitment will be the same as for surgery except for about 5 minutes at 30 and 90 days following surgery to answer some questions over the telephone regarding any complications you may have had.

6. What will happen in this study?

This is a single-center study in which we will do HP in liver surgery patients and collect information about the number of patients transfused, amount of blood transfused and any complications. If you do decide to participate, we will also require access to your medical record to collect demographic information (i.e., age, sex, body mass index), surgical characteristics, liver resection technique, fluids administered, blood loss, medications administered) and physiological measures (heart rate, blood pressure, etc.) and laboratory measures (as described below). This information will be compared to that from patients who had liver surgery at KGH without HP. With participation, you will also receive a telephone call from a team member 30 and 90 days after surgery to ask about any complications. With your approval, we may also contact you by phone or email or access your medical record 5 years after surgery to see if the cancer came back.

7. Alternative

If you decide not to participate you will have your liver surgery without HP, no information will be collected from you for research purposes. You will also not be contacted after surgery and no one will look at your medical record for research purposes.

8. Mandatory Study procedures

If you decide to participate, approximately 10% of your blood volume will be removed via a central venous line or other vascular line (which is already used as part of standard of care for your surgery) and the blood will be re-infused at the end of your surgery while you are still asleep.

If you require more blood/fluids than the amount withdrawn in HP, the anesthesiologist will administer Ringer's Lactate (a standard solution used during surgeries) and possibly blood products in accordance with standard care. If there is a lot of bleeding, transfusion will be started before the low threshold for anemia is reached.

9. Mandatory Non-Experimental Procedures

Blood gases, lactate levels, hemoglobin, and coagulation panels will be conducted at specific points (baseline immediately following induction of anesthesia and before HP, and immediately post HP) to monitor your body's changes to blood volume. This will be done through the lines already in place for your surgery so you will not be poked with needles.

10. Risks

You may experience some risks with participation in this study. The known risks are listed below, however, there may be other unexpected risks that are unknown. You will be immediately informed if we become aware of any new risks that may impact your willingness to participate.

10.1. General risks

If you choose to take part in this study, there is a risk that the HP could potentially result in changes such as blood pressure, heart rate and/or drop in hemoglobin following the blood volume removal, but this will be carefully monitored and immediate action taken as it would as standard care for liver surgery patients.

There is also the risk that you could be identified from the information collected from you but to minimize this risk, all data collected for research will only be identified by a study identification number.

11. Benefits

It is our hope that participation in this study will benefit you by reducing the need for transfusion and its associated complications (as supported by previous research). We hope that the results of this study will benefit future liver resection patients by determining the best practices.

12. Incidental findings

Although unlikely, if any incidental findings result from your participation in this study, you will be immediately notified, and the study team members will arrange for appropriate follow-up during your hospital stay at no cost to you.

13. Withdrawal from the study

You can choose to withdraw from this study at any time without providing a reason. To withdraw your participation from this study or withdraw data already collected, please contact:

Glenio.mizubuti@kingstonhsc.ca or (613) 548-7827

We anticipate publishing 2 reports – after 2-3 years, and after about 5 years. You can withdraw from participation in this study at any point up to 90-days following surgery at which point, any information collected from you will not be used for publication of the first report. After this time, you can still withdraw at anytime prior to the second report and no information about your cancer recurrence will be used for research purposes.

14. When can participation in this study end early?

The Principal Investigator, member of the study team, or HSREB may stop your participation in the study early, without your consent, for the following reasons:

- The surgeon or the anesthesiologist have any safety concerns about your participation.
- The research ethics board withdraws permission for this study to continue.

15. Confidentiality

All the information collected during the research study will remain strictly confidential to the extent permitted by the applicable laws. If you decide to participate in this study, the research team will only collect the information needed. All data will be stored on site. The information collected may be used for presentation or publication, but you will not be identified. All efforts will be made to protect your privacy, and the likelihood that someone may identify you is small, however it cannot be eliminated.

All data will be identified only by a study identification number and stored on the KHSC server in a password-protected file. The master file that links your identity to the data will be stored separately from the data in a password-protected file on the KHSC server. The study data will be stored for 5 years as required by Queen's University following which it will be permanently deleted and/or destroyed by Dr. Mizubuti or his delegate.

The custodian of the study data for the duration of the retention period will be Dr. Mizubuti or his delegate. There are organizations and their representatives that may look at or receive copies of some of the information in your study records and in some cases, your medical record, for data analysis and quality assurance for monitoring, control, safety and security. These may include members of the study team, as delegated by the study doctor or principal investigator; authorized representatives of Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

The following study data will not leave KHSC:

- Demographic information: Age, sex, body mass index, American Society of Anesthesiologist's (ASA) classification
- Surgical characteristics and postoperative complications, description of surgical procedure, blood loss, urine output, fluids and medications administered, complications (including transfusion required, infection, cardiac complications)
- Hemodynamic measures - Heart rate, blood pressure, etc.
- Serial blood lab measures (hemoglobin, blood gases, lactate, measures of kidney and liver function, measures of coagulation, will be collected at baseline immediately following induction and before HP, immediately post-HP and at the end of the liver resection. Samples will be taken directly from the arterial line or the central venous catheter both of which are standard of care for your surgical procedure.

16. Information about this study

You will be informed during the study of any new information that might affect your decision to participate.

17. Reimbursement

There are no costs to you associated with study participation. You will not receive any compensation and no incentives are being offered for participation in this study.

18. Research related injury

If you are injured from participation in this study and need medical treatment, please talk with your study doctor immediately about your treatment options. In case of injury associated with participation, appropriate medical care will be provided at no cost to you.

19. Contact information

If you have questions about this study or if you suffer a research-related injury, you can contact:
Dr. Glenio Mizubuti at glenio.mizubuti@kingstonhsc.ca or (613) 548-7827
For ethics concerns, please contact HSREB at 1-844-535-2988 (Toll free in North America) or email researchethics@queensu.ca.

20. Consent and signatures

By signing or providing consent, I agree that:

- I have read the Informed Consent Form.
- I have had all my questions answered.
- I have been provided adequate time to consider participation.
- I have been directed to keep a copy of the ICF for my records.
- A signed original copy of the ICF will be kept by the research team.
- By consenting, I have not waived any legal right in the event of research-related harm.

I consent to participate in the main study

Yes ☐ No ☐

I consent for my medical record to be accessed 5 years
postoperatively

Yes ☐ No ☐

I consent to be contacted 5 years postoperatively

Yes ☐ No ☐

Tel: _____ **Email:** _____

Signature of Participant

Printed Name

Date

Signature of Person Conducting the
Consent Discussion

Printed Name

Date