Study Title

Hepatic Vein Flow During Orthotopic Liver Transplantation as Predictive Factor for Postoperative Graft Function

NCT03814031

03/18/2019

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| | **CONSENT TO PARTICIPATE IN A RESEARCH STUDY**<br><br>(HFH IRB form rev: 12/7/2018) | DATE:<br><br>MRN:<br><br>NAME: |
| | **PROJECT TITLE: Intraoperative assessment of Hepatic Vein Flow during orthotopic liver transplantation as a prognostic tool for postoperative course** | |

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## 1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

| **Key Information for You to Consider** |
|---|
| **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.<br><br>**Purpose**. The purpose of this research is to measure hepatic vein (one of the vessel draining blood from new liver graft) flow and assess its predictive value for assessing new graft function.<br><br>**Duration**. It is expected that your participation will last from now until your new liver graft is functioning. |

**Procedures and Activities**. You will not be asked to take any action for participating this study. We just measure one additional measurement using existing transesophageal echocardiography and follow your recovery by reviewing medical charts.

**Risks**. No additional risk related to this additional measurement will be anticipated. However, risks of intraoperative esophageal echocardiography may apply. If any complications should be occurring, we will discontinue the study. More detailed information can be found in the "What Are The Risks, Discomforts, And Inconveniences Of The Study?" section in the Consent Form.

**Benefits**. The information learned from your participation may help others in future as well as help for your care.

**Alternatives**. Participation is voluntary and the only alternative is to not take part in this research study.

## 2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The investigators, including Yoshihisa Morita (Principal Investigator (PI)), in this study are also healthcare providers. Yoshihisa Morita has nothing to disclose. The investigators are interested in the knowledge to be gained from this study and are interested in your well-being. Henry Ford Health system (HFHS) receives no funding from to help cover administrative costs such as record keeping, mail and telephone expenses. Investigators don't receive salary or other financial support from the study sponsors in exchange for conducting this study.

## 3. WHY IS THIS RESEARCH BEING DONE?

This research is to measure hepatic vein (one of the vessels which drain blood from liver) flow using a transesophagael echocardiography, which is already a part of standard care for liver transplantation. We will need 62 participants to assess appropriately our hypothesis. This study will be conducted only at Henry Ford sites.

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You have been asked to take part in this study because you have end stage liver disease which require liver transplantation, and transesophageal echocardiography is part of standard care. The purpose of this research study is to assess flow of hepatic vein (one of major vessel which drain blood from the liver) and assess its correlation with new liver function.

Purpose of this study is to assess the correlation between our measured hepatic vein flow and postoperative liver function.

## 4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

We will add one more measurement using existing transesophageal echocardiography (again, transesophageal echocardiography is part of the standard care in liver transplantation). We also assess postoperative liver function using usual methods (follow up blood work, ultrasound, etc). No additional intervention or time related to this study is anticipated.

If you agree to take part in this study, your participation in this study will last a total of time until your liver function is optimal. There is no additional preoperative workup or postoperative workup anticipated.

If we realize significant abnormal findings which are related to this study, we will disclose to surgery team immediately.

## 5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?

Although the researchers believe there are no reasonably foreseeable risks associated with this research study, there may be additional risks or discomforts that are not known at this time. Also, the risk of transesophageal echocardiography might apply, such as sore throat, esophageal trauma, stomach trauma, vocal cord trauma, although these are rare. If we notice these complications, we will discontinue the study a soon as possible.

The researchers will try to minimize these risks by gentle insertion of transesophageal echocardiography using a lubricant, close monitoring of orogastric suction tube.

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled “How will my personal information be protected?”

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

## 6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

Your participation in this study might be beneficial to you because this additional measurement would predict postoperative liver function, and might lead to preemptive intervention if needed.

You may not directly benefit from this research; however, we hope that others are helped in the future by what is learned.

## 7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

You have alternative options of not participating this study. We still do the transesophagael echocardiography assessment if benefits are higher than the risks.

Participation is voluntary. You do not have to participate in this study.

## 8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or specimens in a separate location. The researchers will maintain all study records (including any codes) in a locked, secure location. Your research information will be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any

publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers. The record will be kept in your medical record indefinitely.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without your additional informed consent.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

## 9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

## 10. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Yoshihisa Morita, MD (principal investigator) or his/her staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Yoshihisa Morita, MD by phone at 313-970-1282 or by email at ymorita1@hfhs.org. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org. The IRB is a group of people who review the research to protect your rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## 11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

Your participation is voluntary. You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

## 12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons. This situation might apply to, but not limited to, complications associated with transesophageal echocardiography.

## 13. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

## 14. WILL I BE PAID TO PARTICIPATE?

There is no compensation available to you for your participation in this study.

## DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

The researchers in this study might want to ask you to participate in additional studies. In some cases, you might be a good candidate for a particular study because of your health history or genetic information.

I am willing to be contacted for future research studies. Please initial below.

_____ I agree

_____ I refuse

I understand that my de-identified genetic information may be placed in a repository and shared with other researchers for future research. Please initial below.

_____ I agree

_____ I refuse

I understand that this study involves optional participation in a sub-study. I understand that it is my choice whether or not to take part in the sub-study. Please initial below.

_____ I agree to take part in the optional sub-study.

_____ I refuse to take part in the optional sub-study.

_____ _____ _____

Signature of Subject Date Time

_____

Printed Name of Subject

_____ _____ _____

Witness to Signature Date Time

_____ _____ _____

Signature of Person Obtaining Consent Date Time

_____

Printed Name of Person Obtaining Consent

I am unable to read but this consent document has been read and explained to me by _____ (name of reader). I volunteer to participate in this research.

_____ _____ _____

Signature of Subject/Representative Date Time

_____

Printed Name of Subject/Representative (and Relationship if Someone other than the Subject)

_____ _____ _____

Witness to Signature Date Time

_____ _____ _____

Signature of Person Obtaining Consent | Date | Time

_____

Print Name of Person Obtaining Consent