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Study Title: Phase I clinical trial utilizing direct peritoneal resuscitation in liver transplant recipient population at increased risk of return to the operating room and early allograft dysfunction.

You are being asked to be in a research study because you are about to have a liver transplant. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study is being conducted to assess the safety of Direct Peritoneal Resuscitation (DPR) in high-risk liver transplant patients. We want to also identify if this method of recovery after large surgery has the same benefits in liver transplant patients as have been appreciated in other surgical patients. The reason you are classified as a high-risk liver transplant recipient is due to your body mass index (BMI) and kidney function. The combination of elevated BMI and impaired kidney function increases your risk of 1) needing intensive care unit (ICU) admission after surgery, 2) slow function of your new liver [technically termed Early Allograft Dysfunction (EAD)] and 3) need for more than one operation. We also aim to identify if DPR can reduce these risks and not cause other unexpected complications following surgery. DPR involves the infusion of a solution into the abdomen and has been shown to reduce edema and improve blood flow in organs. The solution used in this study is a commercially available peritoneal dialysate, a dextrose containing solution that is infused into the abdominal cavity and is routinely used in patients with end-stage renal disease requiring dialysis.

You are being asked to be in this research study because you have been evaluated for a liver transplant. Given your disease process and co-morbidities, you have been identified as having a higher risk needing an ICU admission, experiencing poor initial function of your transplanted liver, a condition known as EAD, and/or needing a re-operation after your liver transplant. Considering these risks, you may benefit from DPR in the hours after your surgery.

Other people in this study

Up to *15* people from your area will participate in the study in this initial phase.

What happens if I join this study?

If you join the study, your liver transplant will proceed as it normally would until near the end of your surgery. At this time, one drain will be placed inside your abdomen in addition to the routine surgical drains that are placed as part of the standard of care. This extra drain will be

used for dialysate infusion for up to 24 hours after your surgery. Outflow will be provided by the three intraabdominal drains placed as part of our standard practice.

The duration of the DPR will depend on your surgeon's assessment of your condition at the end of surgery. While our liver transplant patients are frequently admitted to the transplant ward at the end of their procedure, some require an ICU admission for close monitoring based on a variety of factors that impact their stability at the end of the case. If at the end of your case you are deemed safe to be admitted to the transplant ward, you will undergo direct peritoneal resuscitation for 8 hours while in the post anesthesia care unit (PACU), prior to being transferred to the ward. On the other hand, if you will be admitted to the Surgical Trauma Intensive Care Unit (STICU), the dialysate will run for up to 24 hours after your surgery. The drains will then be sequentially removed in the following days as you recover from your liver transplant, which is the standard of care for any surgical drain placed in our practice.

In addition, we will gather basic data from your electronic medical record, starting from the time of your first transplant evaluation visit and up to 90 days after your surgery.
Participation in this study may increase the time spent in your evaluation by 15-20 minutes. Study follow-up information will be gathered from your medical record and will not require you to come to the transplant program any study-specific reasons.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include having an additional abdominal drain, which may cause pain and irritation at the skin incision site. In addition, as with all types with peritoneal dialysis, some patients may experience discomfort described as "crampy pain" at the beginning and/or end of infusion. This can be due to tube position and is sometimes referred to as "drain pain". Lying or sitting in a different position can help alleviate this discomfort.

As mentioned, this study involves the placement of an extra drain in the abdomen. This drain requires an additional small incision in the skin like the other drains placed. There is a risk of a small scar from this incision. The risk of bleeding from this drain site is the same risk as other drains placed. This occurs under direct visualization and should have less than 1% risk of causing additional bleeding. The risk of injuring other organs such as intestine is less than 1% from placement of the drain. The risk of the drain wrapping around bowel causing obstruction is estimated to be less than 1%.

The dialysate solution infused in your abdomen contains sugar. There could be potential risk of requiring insulin beyond 24 hours, which is common in our patient population but unclear without conducting this research if DPR would increase this risk.

The infusion of dialysate into the abdominal cavity after surgery comes with a risk of infection. The dialysis solution in this study will be administered within hospital sterile conditions and the duration will be 24 hours or less. We would anticipate that risk of infection with DPR infusion is less than 5% in the first 7 days and less than 10% in the first 30 days.

With infusion of DPR in a closed abdomen there is a risk that the fluid introduced causes increased abdominal pressure resulting in organ failure. This occurs in the setting of occluded drains. Our protocol dictates strict monitoring of inflow and outflow to reduce this risk. We would anticipate a less than 1% risk of compartment syndrome requiring an urgent re operative intervention and a 10% risk of stopping DPR early to prevent development of compartment syndrome.

There is also a risk of developing an abdominal wall hernia with peritoneal dialysis. However, with the short duration of infusion in this study we do not anticipate a higher risk with DPR. The risk of an acute breakdown of your surgical incision (fascial dehisce) from DPR is a theoretical risk, that we estimate to be less than 1%.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the safety of direct peritoneal resuscitation in the setting of liver transplants in patients with elevated risks.

However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks.

Are there alternative treatments?
At this time standard of care involves using diagnostic tools, such as blood tests and imaging studies to diagnose and react to complications associated with high risk liver transplant patients. There is no specific preventive intervention.

Who is paying for this study?

This study is funded by an Academic Enrichment Fund (AEF) Grant from the Department of Surgery at University of Colorado Anschutz Medical Campus.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you are hurt by this research, we will give you medical care. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the investigator will determine if your injury or illness is research-related. The term "research-related injury" means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the trial.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Hunter Moore. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Moore at 720-848-0005. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Moore with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

What happens to data collected in this study?

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

University of Colorado Denver | Anschutz Medical Campus
University of Colorado Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Hunter B. Moore, M.D., Ph.D.
Division of Transplant Surgery
University of Colorado, Denver
1635 Aurora Ct, C-318
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.

People at the Colorado Multiple Institutional Review Board (COMIRB)

The study doctor and the rest of the study team.

Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)

Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals s involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

The data, tissue, blood, or other specimens given by you to the investigators for this research no longer belong to you.

Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
If data, tissue, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
Any product or idea created by the researchers working on this study will not belong to you.
There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

Signature:_____ Date:_____

(Select one: /*Legally Authorized Representative* **OR** g*Proxy Decision Maker*)

Print Name:_____

Witness Signature: _____ Date:_____

Print Name:_____

Witness of Signature

Witness of consent process