Peritoneal vacuum therapy to reduce the systemic inflammatory insult from intra-peritoneal sepsis/injury/hypertension: a randomized comparison of baseline wall suction versus the KCL AbThera™ Abdominal Dressing.

SPONSOR: Calvin, Phoebe and Joan Snyder Chair for the Translational Research in Critical Care Medicine, Department of Critical Care Medicine

INVESTIGATORS:

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This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

You and/or your legally authorized representative (LAR) are being asked to participate in this study because you have been admitted to the intensive care unit (ICU) and are being treated for intra-abdominal hypertension (IAH). We believe this hypertension is caused by inflammatory mediators (such as IL-6) present in your blood as well as in the liquid building-up in your abdomen. To relieve the pressure, your doctor has opened your abdomen and is draining the fluid out of your abdomen with either a baseline wall suction (provided by the "Stampede VAC" system) or with the KCL AbThera™ Abdominal Dressing. This fluid is called "peritoneal fluid".

The decision to leave your abdomen open would have been a complex one that reflects the severity of your underlying injuries/illness and is one that can only be made by the surgeon in charge while in the operating room, and not any sooner. Which dressing to use temporarily will have been randomly selected for the purpose of this study and cannot be changed until your next operation. There is no proof that any dressing is better than another and no matter which one was chosen, your surgical/ICU team will be trying as hard as they can to try and close your abdomen as soon as it is safe by using a number of possible techniques.

WHAT IS THE PURPOSE OF THE STUDY?

1. To determine if the KCL AbThera™ Abdominal Dressing can significantly reduce the blood concentration of IL-6 when compared with the "Stampede VAC" system.
2. To better understand how the body responds to the inflammatory process that naturally occurs during and after an episode of intra-abdominal hypertension.
3. To identify signals or markers of inflammation and infection as well as its progression and outcome. This includes studying the behaviour of your immune cells.

WHAT WOULD I HAVE TO DO?

If you and/or your legally authorized representative (LAR) agree to participate and sign this consent form you will have the equivalent of ~1 tablespoon of blood (16 ml) taken on days 1, 2, 3, 7 and 28 after the start of this study. The blood will be drawn from an existing IV or an arterial line that is already in place to monitor your blood pressure while in ICU. No new needle sticks will be necessary and no samples will be collected after you are discharged from ICU. Blood drawn for study purposes will be timed with regular blood work. This small amount of blood is in addition to the regular blood work that is being ordered by the doctors who are caring for you. In addition, the peritoneal fluid being drained from your abdomen will be collected on days 1, 2, 3, 7 and 28 or until your abdomen is closed by your treating physician. Aside from blood and peritoneal fluid samples, no other material will be collected.

WHAT ARE THE RISKS?

The risks of the study are minimal since only blood will be collected specifically for study purposes. This will be drawn from an existing line. There is a possibility of discomfort at the site of the catheter, a small amount of bruising and the remote possibility of contracting a secondary infection. All appropriate measures will be taken to minimize these risks. The collection of the peritoneal fluid will not cause you any discomfort as it is usually discarded.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study there may or may not be a direct medical benefit to you. Your condition may improve, worsen or stay the same during the study and there is no guarantee that this research will help you. The information we get from this study may help us to provide better treatments in the future for patients with intra-abdominal hypertension.

DO I HAVE TO PARTICIPATE?

Participation is voluntary. You do not need to participate to receive treatment for your intra-abdominal hypertension. You may withdraw consent at anytime and for any reason without jeopardizing your care. If new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

Your participation in this study will not result in any cost to you or any payment to participate.

WILL THE RECORDS BE KEPT PRIVATE?

By signing this consent form you authorize (allow) the study doctor and his team at the University of Calgary and the Alberta Health Services / Alberta Health Services to use and release coded information from your Study Records. All personal information will be kept confidential and private. Only a limited number of individuals associated with this study will have access to information that may be linked to you. A unique identification number will be assigned to every participant so that names and personal information will not be revealed to the other individuals associated with this study. Any information recorded on paper will be kept in a locked filing cabinet inside of the locked tissue bank facility. Where data has been entered into a computer, access to information will require a secure access code and the actual database will be password protected.

If you agree to participate, your authorization to use and disclose your Study Records has no expiration date. However, you can withdraw (take back) your consent to use and disclose your Study Records whenever you want. You can do this by giving notice to Dr. Kirkpatrick at (403) 944-2888 informing him that you want to withdraw your authorization to use and disclose your Study Records. If you withdraw your authorization, you will need to send a written request as well as give notice by phone to Dr. Kirkpatrick.

All publications that result from the use of your samples will be blinded and will not identify you by name.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the Calvin, Phoebe and Joan Snyder Chair for Translational Research In Critical Care Medicine, the Department of Critical Care Medicine, the University of Calgary, the Alberta Health Services or the Researchers. You and the person you represent will still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

Contact Name:
Second Contact Name:
Contact Phone #: ( )
Second Contact Phone #: ( )

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and you agree to participate. In no way does this waive your legal rights nor release the investigators, or involved institutions, from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Andrew Kirkpatrick (403) 944-2888
ICU Research Coordinator
(Christine Skinner)
at (403) 944-3414

If you have any questions concerning your rights as a possible participant in this research, please contact The Director, Office of Medical Bioethics, University of Calgary, at 403-220-7990.

Participant's Name	
Surrogate (LAR) Name (Relationship)	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.
A signed copy of this consent form has been given to you to keep for your records and reference.

REGAINED CAPACITY CONSENT FORM

Because your illness or injury made it impossible for you to participate fully in the informed consent process, the consent was obtained from your surrogate on your behalf. Your surrogate believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research project.

Informed consent is essential throughout a research project. This means in your situation, you are now being given the opportunity to agree or disagree with the decision made by your surrogate for you to participate. Should you choose to withdraw from the study, any information or material that was obtained before when the researchers were acting on your surrogate's consent for your involvement will be removed from our database and tissue bank. It is your choice whether you wish to remain or withdraw from the study.

Please check the appropriate boxes to indicate your decision:

- ❑ I agree with my surrogate's decision.
- ❑ I do not agree with my surrogate's decision.

- ❑ I wish to remain in the study.
- ❑ I wish to withdraw from the study.

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Andrew Kirkpatrick: **403-944-2888**

If you have any questions concerning your rights as a possible participant in this research, please contact The Director, Office of Medical Bioethics, University of Calgary, at 403-220-7990.

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