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INFORMATION AND CONSENT FORM

Research Study Title:	**Effect of Hyperinsulinemic Normoglycemic Clamp (HINC) on infectious complications following major abdominal and vascular surgery. A randomized controlled trial.**
Protocol number:	2019-4623
Researcher responsible for the research study:	Dr. Thomas Schricker
Co-Investigator(s)/sites:	Dr. Hiroaki Sato (Department of Anesthesia, RVH, MUHC) Dr. Albert Moore (Department of Anesthesia, RVH, MUHC) Dr. Ralph Lattermann (Department of Anesthesia, RVH, MUHC) Dr. Fanco Carli (Department of Anesthesia, MGH, MUHC) Dr. Francesco Denatelli (Department of Anesthesia, MGH, MUHC) Dr. Oren Steinmetz (Department of Surgery, MUHC) Dr. Kent Mackenzie (Department of Surgery, MUHC) Dr. Peter Metrakos (Department of Surgery, MUHC) Dr. Prosanto Chaudhury (Department of Surgery, MUHC) Dr. Charles Frenette (Infection Prevention and Control Service, MUHC) Dr. Barry Stein (Department of Surgery, MUHC) Dr. Sender Liberman (Department of Surgery, MUHC) Dr. Patrick Charlebois (Department of Surgery, MUHC) Dr. Liane Feldman (Department of Surgery, MUHC)
Sponsor:	No Sponsor

INTRODUCTION

We are inviting you to take part in this research study because you are about to have major abdominal (liver/pancreas/colorectal/solid organ transplantation) or vascular surgery.

However, before you accept to take part in this study and sign this information and consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

This form may contain words that you do not understand. We invite you to speak to the researcher responsible for this study (the "study doctor") or to other members of the research team and ask them to explain to you any word or information that is unclear to you before you sign this form.

BACKGROUND

Insulin is a hormone produced by the pancreas. Mainly, it allows blood sugar to enter the body's cells, thereby lowering blood glucose levels.

Patients having major abdominal or vascular surgery often have abnormal blood sugar levels. In this situation, insulin is often used to control blood sugar levels, sometimes in very high doses. In a previous study we have observed that besides lowering blood sugar levels, insulin during surgery may reduce infections after the operation.

PURPOSE OF THE RESEARCH STUDY

It is routine during surgery for the anesthesiologist to give insulin to help prevent abnormal blood sugar levels. The purpose of this study is to see if a new procedure using a "hyperinsulinemic-normoglycemic clamp" can help reduce infection after major abdominal or vascular surgery. The new procedure involves giving higher doses of insulin than you would normally be given during surgery. The hyperinsulinemic-normoglycemic clamp has so far been tested in 30 patients.

For this research study, we will recruit 430 participants, men and women, aged over 18 years old.

DESCRIPTION OF THE RESEARCH PROCEDURES

This research study will take place at Royal Victoria Hospital and Montreal General Hospital, McGill University Health Centre.

1. Duration and number of visits

Your participation in this research project will last 30 days and will include daily visits in your room while you are in the hospital. Once you are discharged from the hospital, you will not be contacted directly anymore. However, information from your medical record will be used to assess signs of infections for 30 days after the operation.

2. Study drug

When participating in this research project, you will be assigned to one of the following groups:

Group 1: You will receive large doses of insulin during your surgery.
Group 2: You will receive the usual amount of insulin during surgery.

The control (Group 2) in this research study will be offered standard care. This means that people in group 2 will receive the amount of insulin that is routinely given during surgery. We are using a control to compare with the study group (Group 1) and to ensure that the changes you report in your health, good or bad, are not only due to chance. In this information and consent form, the use of "study drug" refers to the drug being studied in both groups.

Furthermore, this study is randomized which means that you will be assigned to one of the groups. You may not choose the group to which you will be assigned; this process is done randomly like flipping a coin. One person out of 2 (50 %) will be in group 1 (study group) whereas one person out of 2 (50 %) will be in group 2 (control group.)

This is a double blind study, which means that neither you, the study doctor, nor the research team will know which study drug you will receive during this project. The anesthesiologist who is treating you in the operating room will know to which group you have been assigned. In case of emergency, the study doctor will have access to this information.

3. Tests and procedures

During your participation in this research study, the study doctor or a member of the research team will conduct the following tests and procedures:

DESCRIPTION OF STUDY PROCEDURES	
Procedure	**Description**
Blood Glucose Test	Your blood Sugar will be tested every 5 to 30minutes to make sure that it is controlled well during surgery. There will be no extra needle-stick required because the blood sample for the glucose test will be taken from the IV line that is already in place.
Glucose monitoring (Continuous glucose monitor)	Blood glucose will be monitored by a continuous glucose monitor on your abdominal or upper arm area. The glucose sensor with a soft catheter is inserted, and it automatically measure your blood glucose. Calibration may be performed and may require a finger prick, which will be done by a research staff. This monitoring is conducted solely for the purpose of the study.
Intravenous Glucose	Extra sugar will be intravenously given if necessary to adjust your blood sugar level during surgery
Intravenous Insulin	Intravenous insulin will be given at large dose in the study group and at a regular dose in the control group

Infectious assessment	During your hospital stay, a member of the study team will monitor you daily for signs of infection. This will involve checking surgical wound for pus discharge, pain, tenderness, swelling redness, heart or dehiscence. Assessment of deep infection can involve ultrasound or other imaging, including X-ray and CT.
Review of your medical records	Your medical records will be reviewed up until 30 days after your surgery to monitor for infection.

The schedule of procedures for each visit is listed below:

SCHEDULE OF STUDY PROCEDURES			
Procedure	**Before Surgery**	**During Surgery**	**During Hospital Stay**
Blood glucose Test	X	X	
Glucose minitoring	X	X	X
Intravenous Glucose		X	
Intravenous Insulin		X	
Infectious Assessment			X

PARTICIPANT'S RESPONSIBILITIES

- Follow the directions of the research team;
- Report any changes in your health to the research team;
- Report any problems that you experience that you think might be related to participating in the study;

BENEFITS ASSOCIATED WITH THE RESEARCH STUDY

You may or may not personally benefit from your participation in this research project. However, we hope that the study results will contribute to the advancement of scientific knowledge in this field and help us find better treatments for patients.

RISKS ASSOCIATED WITH THE RESEARCH STUDY

The study is experimental and therefore we may not know all the discomforts, side effects and other possible risks associated with it.

Therefore, if you have noticed side effects, whatever they may be, during this research study, you must tell the study doctor immediately, regardless of whether you think these effects are related to the study drug. Even once your participation in the study is over, do not hesitate to contact the study doctor if you experience a side effect that may be linked to the study drug.

The study doctor and members of his or her team will answer any questions that you may have regarding

the risks, discomforts and side effect associated with this study. Also, at each visit, the study doctor and members of his or her team will ask you questions about any side effects you may have experienced.

You will find below a list of the side effects a with the study drug.

1. Risks associated with the study drug.

- There is a risk that insulin, like any other medication, could provoke an allergic reaction in people who receive it. This allergic reaction could range from mild to life-threatening. Symptoms of a life-threatening allergic reaction (called anaphylaxis) may include difficulty breathing, rapid heartbeat, tongue swelling, nausea, fainting, hives, fever, and dizziness. If the anesthesiologist believes you are having an allergic reaction, it will be treated with optimum care.

2. Risks associated with research procedures.

- Hypoglycemia: The risk associated with this study is very small and include an abnormally low blood sugar which can cause sweating, dizziness, tremors, and rarely seizures. All precautions will be taken to prevent this from occurring.
- Glucose monitoring: Blood sugar may be measured with finger pricks by lancets, which may cause slight discomfort. A continuous glucose monitor will also be used. It has a sensor either on your abdominal or upper arm area. The sensor has a soft catheter inserted in your subcutaneous tissue to measure glucose. Inserting the sensor and wearing the adhesive patch might cause a slight discomfort, infection, bleeding, pain, or skin irritations (for example, redness, swelling, bruising, itching, scarring, or skin discoloration). The chance of this happening is low. The sensor may cause slight redness and swelling.

RISKS ASSOCIATED WITH PREGNANCY

Participation in this study may include risks, known or unknown, for pregnant women, unborn children or to children of breastfeeding women. Consequently, pregnant or breastfeeding women cannot take part in this project.

If you suspect that you have become pregnant during your participation in the research study, you must inform the study doctor immediately in order to discuss different options with him or her.

OTHER POSSIBLE TREATMENTS

You do not have to take part in this study to receive medical care for your condition. If you choose not to participate in this study, you will still receive standard care. We encourage you to discuss with the study doctor all available options.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study

doctor or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the study doctor or clinical team.

The study doctor, the Research Ethics Board, the funding agency, or the Sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

If you withdraw or are withdrawn from the study, the information and biological material already collected for the study will be stored, analyzed and used to ensure the integrity of the study.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

CONFIDENTIALITY

During your participation in this study, the study doctor and their team will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of the study.

The study file may include information from your medical chart, including your identity, concerning your past and present state of health, your lifestyle, as well as the results of the tests, exams, and procedures that you will undergo during this research project. Your research file could also contain other information, such as your name, sex, date of birth and ethnic origin.

All the information collected during the research project will remain strictly confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept by the study doctor.

To ensure your safety, a copy of this information and consent form will be placed in your medical chart. As a result, any person or company to whom you give access to your medical chart will have access to this information.

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The study data will be stored for 25 years by the study team.

The data may be published or shared during scientific meetings; however it will not be possible to identify you.

For monitoring, control, safety, security, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as

well as by representatives of the institution, or the Research Ethics Board. All these individuals and organizations adhere to policies on confidentiality.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

However, in order to protect the scientific integrity of the research project, accessing certain information before the project is ended may require that you be withdrawn from the study.

INCIDENTAL FINDINGS

Material incidental findings are unexpected findings made in the course of the study that may have significant impacts on your current or future wellbeing or that of your family members. A material incidental finding concerning you in the course of this research will be communicated to you and to a health professional of your choice.

MARKETING POSSIBILITIES

The research results, including those following your participation in this study, could lead to the creation of commercial products. However, you will not receive any financial benefits.

COMPENSATION

You will not receive financial compensation for participating in this research study.

SHOULD YOU SUFFER ANY HARM

Should you suffer harm of any kind following administration of the study drug, or following any other procedure related to the research study, you will receive the appropriate care and services required by your state of health.

By agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the study doctor, the sponsor or the institution, of their civil and professional responsibilities.

CLINICAL TRIAL REGISTRATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any moment.

CONTACT INFORMATION

If you have questions or if you have a problem you think may be related to your participation in this research study, or if you would like to withdraw, you may communicate with the study doctor or with someone on the research team at the following number: Dr. Lattermann at 514 934 1931 ext 36423.

For any question concerning your rights as a research participant taking part in this study, or if you have comments, or wish to file a complaint, you may communicate with:

> The Patient Ombudsman of the McGill University Health Centre at the following phone number: 514 934 1934 ext. 48306.

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH

The McGill University Health Centre Research Ethics Board reviewed this research and is responsible for monitoring the study.

Research Study Title: Effect of Hyperinsulinemic Normoglycemic Clamp (HINC) on infectious complications following major abdominal and vascular surgery. A randomized controlled trial..

SIGNATURES

Signature of the participant

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.

I authorize the research study team to have access to my medical record for the purposes of this study.

- I authorize the study doctor to inform my treating physician that I am taking part in this study:

  Yes ☐
  No ☐

I understand that the study doctor will send my treating physician health information if it will be useful for my care.

Name of participant Signature Date

Signature of the person obtaining consent

I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions.

Name of the person obtaining consent Signature Date

Commitment of the principal investigator

I certify that this information and consent form were explained to the research participant, and that the questions the participant had were answered.

I undertake, together with the research team, to respect what was agreed upon in the information and consent form, and to give a signed and dated copy of this form to the research participant.

Name of the principal investigator Signature Date

Article information: https://dx.doi.org/10.21037/atm-22-3721