TITLE: Cerebral Oximetry in Post-Cardiac Arrest Treatment: The COMPACT Study

SPONSOR: Canadian Intensive Care Foundation

INVESTIGATOR: Dr. Andreas Kramer
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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.

Your family member was incapable of providing consent due to the severity of his/her illness, so the consent of a relative or other authorized representative is being sought. This consent form is meant for that relative or authorized representative. If at any time during the study, the patient becomes capable of providing consent, informed consent will be sought from them as a condition of their continuing participation. In this consent form, the term "subject" means your family member.

When possible, we do obtain consent from the authorized representative before enrolling the subject into the study. However, sometimes we cannot wait for the authorized representative to obtain consent, as this study has very tight time windows for the subject to be eligible to participate. As the risks in this study are minimal, the subject has already been enrolled in the study. By signing this form, the subject will continue in the study intervention and data collection will continue. If you do not sign, the subject will be removed and no more data will be collected. If at any time during the study, the subject becomes capable of providing consent, informed consent will be sought from them as a condition of their continuing participation.

BACKGROUND

You are being asked to provide consent for this research study on behalf of your family member who is currently hospitalized in the intensive care unit (ICU) following a cardiac arrest with the possibility of "hypoxic-ischemic brain injury" (HIBI) caused by lack of blood flow and oxygen to the brain.

HIBI is a life-threatening condition that may also result in serious long-term physical and mental consequences. It is important to find ways to improve patients' health after suffering HIBI. Even after the heart has been re-started, there may still be inadequate blood flow and oxygen delivery to the brain for a period of time. To reduce the risk of further injury to the brain, doctors usually carefully

control factors that can affect blood flow to the brain (e.g. blood pressure, oxygen and carbon dioxide levels, and blood hemoglobin levels). However, there are no proven tools to continuously measure oxygen delivery to the brain, so doctors are not always sure whether it is adequate.

There is a relatively new non-invasive method of assessing oxygen levels in the front of the brain called "cerebral oximetry", which measures a value called "regional oxygen saturation". It is possible that this could be one way of ensuring adequate oxygen delivery to the brain. When regional oxygen saturation in the brain is low, doctors can raise it by increasing blood pressure, raising carbon dioxide or oxygen levels in the blood, or transfusing blood. However, these measures have never been proven to improve outcomes in patients with HIBI and more research is needed.

WHAT IS THE PURPOSE OF THE STUDY?

We want to see if monitoring brain oxygen levels and then intervening if the oxygen levels reach a low enough level might be beneficial.

WHAT WOULD THE SUBJECT HAVE TO DO?

The subject (your family member) has already been enrolled and into the study. He/she was randomly assigned to one of the following two groups:

1. The first group includes participants in whom care is as usual when there has been a cardiac arrest and the heart has been restarted.
2. The second group includes participants in whom care will be the same as in the first group, except that "regional oxygen saturation" levels will be measured and kept above a minimum level (60%) as much as possible.

Which group they were assigned to was decided randomly. Randomization means that they were put into a group by chance, similar to flipping a coin. There was no way to predict which group they would be assigned to. They had a fifty-fifty chance of being placed in either group. Neither you, the study staff, nor the study doctors could choose what group they would be put in. The study intervention will last for 48 hours. All other care will be the same.

WHAT IS THE INTERVENTION?

Group 1 (Standard Care): If he/she was randomly assigned to this group, care will be consistent with national and international guidelines. Brain oxygen levels will still be measured in the background, but will not be used to guide care. Brain oxygen is measured using an adhesive pad that is applied to both sides of the forehead.

Group 2 (Standard intervention): If he/she was randomly assigned to this group, brain oxygen levels will be measured and doctors and nurses will use this information to guide treatment. If the "regional oxygen saturation" falls below 60%, measures will be taken to raise it. These measures may include raising the blood pressure with life-support drugs, administering intravenous fluids, adjusting ventilator settings or giving a blood transfusion. The decision about which intervention to use will be at the discretion of the most responsible physician(s).

Participation in the study will last for 72 hours, but we will also need to determine the final outcome at the time of hospital discharge. Participation in the study may be stopped if the subjects' doctor feels it is not in their best interest.

If you consent and your family member remains part of the study, we will collect information from their medical chart throughout their hospital stay. Someone from the research team may follow up with them prior to discharge from hospital.

WHAT ARE THE STUDY PROCEDURES?

Adhesive pads will be applied to the forehead in order to measure regional oxygen saturation in the front of the brain. This will continue for about 48 hours.

During your family member's stay in the ICU, blood will be drawn from their veins or arteries to check blood levels of proteins that are increased in the setting of brain injury. This will occur at the beginning of the study and once daily for three days. The samples will be used only for study purposes. The samples will otherwise not be stored nor sold.

WHAT ARE THE RISKS?

Patients that are comatose following a cardiac arrest often require life-support drugs ("vasopressors") to maintain a sufficiently high blood pressure. If the blood pressure needs to be raised more to increase oxygen delivery to the brain, the higher dose of these drugs could rarely cause heart rhythm disturbances or problems with circulation to other organs.

Carbon dioxide and oxygen levels in the blood are usually tightly regulated with a breathing machine ("ventilator"). The settings on the ventilator might be changed to increase oxygen delivery to the brain. More blood flow to the brain can sometimes result in a higher pressure in the brain, which may become dangerous.

If the subject is in the brain oxygen monitoring group, the subject is slightly more likely to require a blood transfusion. Blood transfusion are not without risk, including the following:

Infrequently (less than 1%)

1. Fever
2. Rash

Rarely (less than 0.1%)

1. Severe allergic reaction that may be life-threatening
2. Transfusion reaction associated with fevers and with damage to red blood cells (RBCs)
3. Injury to the lungs
4. Accumulation of fluid in the lungs

Very Rarely (less than 0.001%)

1. HIV
2. Hepatitis C
3. Hepatitis B

Blood Draws:

Daily blood draws will be needed at the start of the study and for three days afterwards. In almost all cases, blood samples will be collected from an existing tube that has been placed in one of their blood vessels. In the rare exception where this might not be possible, a venipuncture (needle into vein) will be required. This may cause minor discomfort or pain.

WHAT ARE THE REPRODUCTIVE RISKS:

In the very rare case where a cardiac arrest occurs in a pregnant patient, the effects of the proposed interventions are currently unknown.

WILL THE SUBJECT BENEFIT IF THEY TAKE PART?

If you agree for the subject to continue participation in this study there may or may not be a direct medical benefit to the subject. The subject's brain injury may be improved during the study but there is no guarantee that this research will help them. The information we get from this study may help us to provide better treatments in the future for patients with HIBI.

DOES THE SUBJECT HAVE TO PARTICIPATE?

You can choose for the subject to not continue participation in this study. If you choose not to participate, the brain oxygen monitoring will be discontinued and care will, as usual, not be guided by this tool.

Your family member's continued participation in this study is voluntary. You and/or the subject may decide not to continue participation in this study, or to be in the study now, and then change

your/their mind later without affecting the medical care, education, or other services to which they are entitled.

The subject may withdraw from the study at any time without any impact on their current or future care at this institution.

- If you/they decide to stop study participation, you/they should contact the most-responsible doctor or the study team first. They will discuss the related issues or possible safety concerns for the subject.
- If you/they withdraw your/their consent, the study team will discuss with you/them whether you/they will allow for the continued collection of your personal health information for research purposes and whether you/they agree to any further follow up. You/they may choose to have no further follow up and/or have the subjects data withdrawn from the study completely.

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

There will be no charge for participating in this study. The study treatment and study-related procedures will be provided at no charge to you or your insurance company. You and/or the subject will not be given money or otherwise financially compensated to take part in this study.

WILL THE RECORDS BE KEPT PRIVATE?

- If you decide to continue with the study, the investigator(s) and study staff will look at the subject's personal health information and collect only the information they need for this study. "Personal health information" is health information about the participant that could identify them because it includes information such as their name, age, and results of various tests and procedures.
- Health information will be released only if it is required by law.
- All information collected during their participation in this study will be identified with a unique study number (for example participant # FMC01), Records identifying them at this center will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.
- A Master List provides the link between their identifying information and the coded study number. This list will be stored securely at this site and will only be available to Dr. Kramer
- Authorized representatives from the University of Calgary or the Conjoint Health Research Ethics Board may look at the subject's identifiable medical/clinical study records held at Foothills Medical Centre for quality assurance purposes. The subject will not be identified in any publications or presentations resulting from this study.
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- Research records will be kept for 5 years, as required by CHREB, after which all paper records will be shredded and all electronic records securely deleted.

- Increasingly, the scientific community, the granting agencies and medical scientific journals require that data be stored and made available for secondary review and analyses. For publication purposes the de-identified study data may be shared for re-analyses. The subject's coded research data may also be transmitted by the principal investigator to other researchers from other institutions for secondary analyses or other research purposes.

A description of this clinical trial will be available on www.clinicaltrials.gov. This Web site will not include information that can identify the subject. At most, the Web site will include a summary of the results. You can search this Web site at any time.

IF THE SUBJECT SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

In the event that the subject suffers an injury as a result of participating in this research, no compensation will be provided to the subject by the University of Calgary, Alberta Health Services, Canadian Intensive Care Foundation or the Researchers. The subject still has all their legal rights. Nothing said in this consent form alters their right to seek damages.

SIGNATURES

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

Dr. Andreas Kramer (403) 944 -2334
or
Research Coordinator (403) 944-8748

If you have any questions concerning your rights as a possible participant in this research, please contact The Chair of the Conjoint Health Research Ethics Board, 403-220-7990.

Participant's Name	
Surrogate's Name	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.