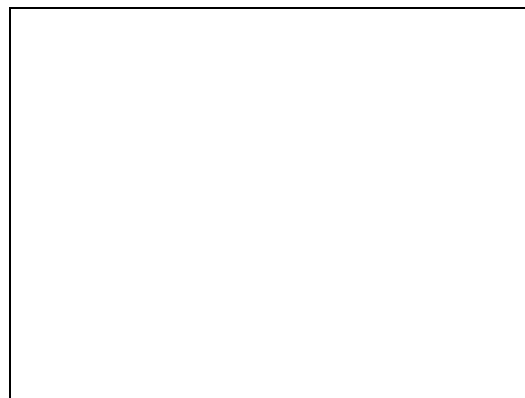


Appendix 5 : Informed Consent Form



Information Sheet and Consent Form

Hemoglobin transfusion threshold in traumatic brain injury optimization: the HEMOTION trial

Principal Investigators:

Dr Alexis Turgeon
Department of Critical Care Medicine
CHU de Québec — Université Laval

Dr François Lauzier
Department of Critical Care Medicine
CHU de Québec — Université Laval

Dr Dean Fergusson
Clinical Epidemiology Program
Ottawa Hospital Research Institute

Local Investigator

LOCAL INVESTIGATOR NAME(S)

Local Co-Investigators:

LOCAL CO-INVESTIGATOR NAME(S)

Granting Agency:

Canadian Institutes of Health Research

Preamble

We request the participation of the person you represent in a research project. However, before accepting and signing this information sheet and consent form, please take the time to read, understand and carefully consider the following information.

This document may contain words that you do not understand. We invite you to ask any questions you may find useful to the Investigator in charge of this project or to the research staff. You may also ask them

to explain any word or information that is not clear.

Objectives of this Research Project

The person you represent is currently hospitalized in the intensive care unit (ICU) following a traumatic brain injury (TBI). TBI is an important cause of disability and can result in severe sequelae. TBI victims often have low hemoglobin levels (anemia) for a variety of reasons. This low level of hemoglobin can lead to additional sequelae by decreasing oxygen delivery to the brain. Generally, doctors prescribe transfusions of red blood cells (blood transfusion) when the hemoglobin is below 70 g/L to maintain oxygen delivery. However, we ignore if it would not be better to aim for higher hemoglobin levels.

The main objective of this study is to evaluate whether maintaining hemoglobin levels above 100 g/L (rather than 70 g/L) with red blood cell transfusions reduces the sequelae caused by the TBI.

This study will take place in several sites across Canada and the UK and will involve approximately 712 patients. The study will last approximately 4 years.

Procedures of the Research Project

If the hemoglobin level of the person you represent is below 100 g/L, the participant will be randomly assigned (such as flipping a coin) to one of two groups:

A computer will randomly determine in which group the person you represent will be assigned. There will be a 50% chance (1 chance out of 2) to be assigned to one of the following groups:

Group 1: Transfusion of red blood cells if the hemoglobin level is less than or equal to 100 g/L

Group 2: Transfusion of red blood cells if the hemoglobin level is less than or equal to 70 g/L

The study intervention will last until you are discharged from the ICU.

The assignment group will not be communicated to you or to the person you represent.

The medical team may have decided to proceed with a blood transfusion as part of this Research Project before obtaining your consent given the urgent need to maintain proper oxygen transport to the brain. If you refuse to allow the person you represent to continue participating, the decision to transfuse will be left to the ICU team. At any time, the physician of the person you represent may terminate study participation if he/she believes it is in the best interests of the participant.

If the person you represent participates in this study, we will collect information from her/his medical record. Her/his contact information will be provided to the coordinating research team. Six months later, a member of the coordinating research team will get in touch with the person you represent to obtain information on the consequences of the TBI, the level of activity, the mental health and the quality of life. This information will allow to evaluate the effect of the study intervention. This should take about 30 to 45 minutes and will be done by phone call or with electronic questionnaires to be completed online (when possible). It is possible that the person you represent will not be able to answer some of the questions due to her/his condition. In this case, we will ask a representative of the patient (yourself or someone else) to answer the questions on behalf of the patient.

Benefits Associated with the Research Project

The person you represent may benefit from participating in this Research Project, but we cannot guarantee this. However, the results of the Research Project will contribute to the advancement of scientific knowledge and may benefit future patients.

Risks Associated with the Research Project

Most patients with TBI will receive red blood cell transfusions during their hospitalization. In this study, patients allocated to Group 1 may receive more transfusions than patients allocated to Group 2.

The risks incurred by study participants are the same as those incurred by non-study patients receiving transfusions.

The side effects of red blood cell transfusions include:

- Uncommon (fewer than 1%)
 - Fever
 - Skin rash
- Rare (fewer than 0.1%)
 - Serious allergic reaction that may be life-threatening
 - Transfusion reactions associated with red blood cell damage
 - Lung injury
 - Fluid overload in the lungs
- Very rare (fewer than 0.001%)
 - HIV, Hepatitis B, Hepatitis C. The Canadian system of blood collection and distribution is safer than ever, but it will never be possible to ensure that blood transfusion is free of any risk of disease transmission or infection.

Disadvantages of the questionnaires:

It is possible that some questions may make you or the person you represent feel uncomfortable. The questionnaires do not generate any other disadvantage, except the time devoted to them.

Voluntary Participation and Possibility of Withdrawal

Participation in this Research Project is voluntary. You, and the person you represent, are free to refuse to participate. You, and the person you represent, can also withdraw at any time by informing the research team, without providing an explanation.

The decision not to participate or withdraw from this Research Project will have no impact on the quality of the care and services provided to the person you represent. It will not have an impact on your relationship with healthcare providers.

The Investigators, the Research Ethics Committee of the *CHU de Québec - Université Laval* and the Canadian Institutes of Health Research may terminate the participation of the person you represent to this Research Project without consent if new discoveries or data indicates that it is no longer in the best interest of the participant, if the participant is unable to comply with instructions or if there are administrative reasons for abandoning the Project.

However, before the person you represent withdraws from this Research Project, we suggest to, for security purposes, make a final evaluation by phone.

In case of withdrawal, the data and material already collected will nevertheless be retained, analyzed and used if necessary to comply with regulatory requirements and ensure the integrity of the project.

Any new knowledge that may affect your decision or the decision of the person you represent to participate will be immediately communicated to you.

Confidentiality

During this project, the Investigators and their staff members will collect and record information of the person you represent in a research folder. Only information necessary to meet the scientific objectives of the project will be collected.

This information may include information contained in medical records regarding past and present health status, lifestyle, and investigation results, physical examinations and procedures that will be performed during this Research Project. This data will be retained by the Investigators for 10 years.

All information collected is strictly confidential to the extent permitted by the law. The person you represent will only be identified by a code number. The key of the code linking the participant's name to the research folder will be kept by the Investigators.

To ensure the safety of the person you represent, a copy of this Information Sheet and Consent Form will be included in the medical record. Therefore, anyone who has access to the medical record will have access to the information that the document contains.

The local investigator will forward the coded research data on the person you represent to the Principal Investigators or their representatives (coordinating team). 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. Your family member'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. It will not be possible to identify any individual including yourself in any publication.

For surveillance, control, protection and safety purposes, the research folder and the medical records of the person you represent may be consulted by Canadian (e.g. such as Health Canada) or foreign regulatory bodies, by representatives of the Canadian Institutes of Health Research, by institutional representatives or by the Research Committee. These individuals and organizations all adhere to a privacy policy.

You have the right to consult the research folder of the person you represent to verify the information collected and have it corrected if necessary. However, to preserve the scientific integrity of the project, you may only be able to access some of this information once their participation in the Research Project is completed.

Compensation

There is no financial compensation for participating in this Research Project.

Indemnity in Case of Injury and Participant's Rights

If the person you represent should suffer any prejudice because of any procedure related to this Research Project, all the necessary care and services required will be provided.

By agreeing to participate in this Research Project, you do not waive any right or release the Investigators, the institution and the Canadian Institutes of Health Research from their civil and professional liability.

Contacts

If you have questions about the Research Project or if the person you represent has problems that you believe are related to their participation in the project, you can contact the Local Investigator (TELEPHONE NUMBER), the research team (TELEPHONE NUMBER) or go to the nearest Emergency Room.

If you have any questions about the rights of the person you represent, or if you have any complaints or comments, you can contact the Local Service Quality and Complaints Commissioner of the *CHU de Québec — Université Laval* at 418-654-2211.

Monitoring ethical aspects of the research project

The Research Ethics Board of the CHU de Québec-Université Laval approved this research project and ensures the follow-up for all participating institutions of the health and social services network of the province of Québec.

Consent Form
(Temporarily Incapacitated Adult Participant)

Title of the Research Project: Hemoglobin transfusion threshold in traumatic brain injury optimization: the HEMOTION trial

Since Mr./Mrs. _____ has been suddenly rendered incapable to consent for the reason identified below, the *Code civil du Québec* authorizes you, as _____ (your relationship with the participant) to consent for the person you represent to participate in this research project.

As soon as Mr. / Mrs. _____ is recovered, we will invite her/him to sign the consent form so that he/she can indicate his/her desire to continue or not to participate in the Research Project.

Reason why the participant cannot consent:

I have read the Information Sheet and Consent Form. The research project and this Information Sheet and Consent Form was explained to me. My questions were answered and I was given the time to decide to participate. After consideration, I consent that the person I represent participates in this Research Project under the conditions defined therein. I also authorize the research team to have access to the medical records of the person I represent.

I authorize the family doctor of the person I represent to be informed of the study participation.

Yes No

Name of the participant (please print)

Name of the person qualified to give consent for care (relationship with the participant)
(please print)

Signature of the person qualified to give consent for care

Date

Signature of the person who obtained consent if different from the Local Investigator

I explained the Research Project and the Information Sheet and Consent Form to the person qualified to give consent for care, and I answered the questions he/she asked me.

Name of the person who obtained consent (please print)

Signature of the person who obtained consent

Date

Consent Form
(Temporarily Incapacitated Adult Participant who Regained Capacity)

Title of the Research Project: Hemoglobin transfusion threshold in traumatic brain injury optimization: the HEMOTION trial

Your legal representative gave consent for your participation in this study because you were not able to decide due to your health condition. Your condition has now improved. We therefore ask you to decide whether you wish to continue your participation in this study. Your decision is voluntary. This means that the decision belongs to you.

You have read the information provided in this information and consent form and someone has explained to you which procedures of the study will be continued. Your questions were answered at your satisfaction. You believe you have understood all the information related to this study.

Participant Consent

I am now able to make my own decisions and:

_____ (initials) I agree to continue my participation in this study.

_____ (initials) I do not agree to continue my participation in this study. I understand that the data already collected may nevertheless be used for this study to ensure its reliability.

Name of the Participant (please print)

Signature of the Participant

Date

Signature of the person who obtained consent if different from the Local Investigator

I certify that the Research Project and this Information Sheet and Consent Form have been explained to the participant. I have answered all the questions and I have made it clear that the participant remains free to terminate his participation, without prejudice.

Name of the person who obtained consent (please print)

Signature of the person who obtained consent

Date