Informed Consent Form for Parents/Guardians of Subjects

Does early higher intravenous lipid intake decrease weight loss in very low birth weight infants? (REB-17-2236)

Primary Investigator: Belal Alshaikh, MD MSc

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Parent/Legal Guardian – Informed Consent Form

Title of Research Project: **Does early higher intravenous lipid intake decrease weight loss in Very Low Birth Weight?**

Investigator(s):

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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 your child's 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

Preterm babies are commonly discharged home with less than optimal weight compared to babies born after 37 weeks gestation. This poor growth during their stay in the hospital is largely related to inadequate nutrition, especially in the first few weeks after birth. Generally speaking, human fetus begins to store large amounts of fat and protein in the last third of pregnancy. Early birth interrupts this process. Because preterm gut is not fully ready to digest milk in the first few days after birth, it is important to provide the needed nutrients through a vein catheter.

Newborns normally lose some weight in the first week of life. This loss is higher in babies born premature particularly those with birth weight less than 1500 g. While weight loss is mainly related to water loss in term infants, low protein and fat intakes in the first week of life play additional role in preterm infants. In the past, physicians used to start preterm babies on small amounts of protein and fat then increase slowly in a stepwise fashion (0.5 to 1 gram per kilogram) to eventually match what they used to get in the womb. Evidence now support the use of higher protein intake (3 grams per kilogram) from the first hour of life to match what the fetus gets before birth. Whether to give higher amount of fat or not right after birth is still to be answered.

We think that giving higher intake of fat that matches what the baby used to get before birth may help reducing the amount of weight loss. It may also help use the high amount of protein to build the body of these small babies. Also, we expect babies who get this appropriate intake will regain their birth weight earlier and grow better during their hospital stay.

WHAT IS THE PURPOSE OF THE STUDY?

We think that if we give small preterm babies higher fat intake, that approximates what they used to receive in the womb, soon after birth they will have less weight loss and shorter time to regain their birth weight.

WHY HAS MY CHILD BEEN ASKED TO PARTICIPATE?

We want to study babies that are born early with birth weight less than 1500 g. Your baby was born with birth weight less than 1500 g, which is the group of infants we want to study.

DOES MY CHILD HAVE TO PARTICIPATE?

Your baby's participation in this research trial is completely voluntary. You can choose whether or not to participate. If you decide not to participate, there are no penalties, and your baby will not lose any benefits to which your baby would otherwise be entitled. If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form.

You are free to withdraw (stop your baby's participation) at any time, without giving a reason and without penalty or loss. Your decision to withdraw will not affect your baby's future medical care.
Should you choose to withdraw your baby from the study, the data already collected will only be kept with your permission.

WHAT WILL HAPPEN TO MY CHILD IF HE/SHE TAKES PART?

This is a randomized controlled study. Your baby will receive after birth either higher intake of intravenous fat or if he/she is in the control group he/she will receive the standard lower dose of intravenous fat.
Apart this this, there will be no difference in the care or feeding of your baby.

WHAT ELSE DOES MY CHILD'S PARTICIPATION INVOLVE?

We will also be reviewing your baby's health record chart to gather information on the history of the pregnancy (including complications and medication used by the mother), the birth (including: gestational age, weight, need for support) and course in the neonatal intensive care units in Calgary (including: diagnoses during hospitalization, feeding and diet history, medications used, laboratory and diagnostic imaging results).

WHAT ARE THE ALTERNATIVES?

Your baby would receive the standard care provided to all babies in NICU with the lower fat intake that is given through his/her vein catheter.

WHAT ARE THE RISKS?

There is a probability of having mild elevation of serum levels of fat. Serum fat levels are routinely checked for all babies started on fat. First measurement is done after 24 hours of starting fat and then after every increase in fat intake until the baby is on 3 grams per kg of fat. Babies with fat levels higher than the normal range will have their fat intake reduced.

ARE THERE ANY BENEFITS FOR MY CHILD?

If you agree for your baby to participate in this study, there may or may not be a direct medical benefit to her/him. Your baby may benefit from participating in this study by reaching her/his targeted fat intake earlier with fewer number of blood tests thus less blood loss. The indirect benefit of participating in our

study is that the results will provide important information on whether giving higher intake of fat improve growth of preterm babies.

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

There is no cost associated for participation in the study. You will receive no payments to have your baby participate in the study.

WILL MY CHILD'S RECORDS BE KEPT PRIVATE?

If you decide to have your baby participate in this research project, your baby's medical records will be reviewed by a research assistant or one of the primary investigators to collect information that will help understand the findings of the study. This information may also be looked at by representatives of the Health Authorities or the University of Calgary Conjoint Health Research Ethics Board, additionally to check that the research trial is being performed correctly. All will have a duty of confidentiality to your baby as a research participant, and a duty to observe any applicable data protection laws.
The information gathered on your baby will be kept confidential, with none of said information being released without your written consent. The results of our study will be reported as group data without any information that could identify the participants in the study. At the end of this research trial, the results may be published or used for teaching. Nothing that could reveal your baby's identity will be included.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by the 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.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

In the event that you or your baby suffers injury as a result of participating in this research, no compensation will be provided to you by The University of Calgary, Alberta Health Services or the Researchers. Nothing said in this consent form alters your right to seek damages.

WHO HAS REVIEWED THE TRIAL?

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

CONTACT DETAILS:

If you have further questions concerning matters related to this research, please contact:

Dr. Belal Alshaikh (403) 955-2320 or
Dr. Wissam Alburaki (403) 483-8903.

If you have any questions concerning your rights as a possible participant in this research, or if you have any complaints or concerns about the way the trial doctors have carried out the trial, you may contact the Chair, Conjoint Health Research Ethics Board, University of Calgary, at 403-220-7990.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your baby's participation in the research project and agree to their participation 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 your baby from the study at any time without jeopardizing their health care.

Parent/ Legal Guardian Informed Consent Form

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- I have read and understood the above information and have been provided with a copy of this Subject or Parent/Legal Guardian Informed Consent form.
- I have had time to think about what is involved if I decide that my baby will participate in this research project.
- I can, at any time, if I want, stop my baby's participation without having to give any reason. I will inform the research team about my decision.
- For the purpose of this registry, I give my permission that members of the research team, and representatives of the health authorities and Ethics Committees may look at my baby's medical records, in respect of the current research trial. I agree to the collection and processing of some of my baby's personal medical data.
- By signing this form, I have not waived any legal rights I otherwise would have as a parent/legal guardian of a participant in a research trial.

If you have any unanswered questions or unsatisfactory answers to your questions, do not sign this form.

Name of subject:…….

Name of subject's parent or legal guardian:……

Relationship to subject: ……..

Signature: …… Date _____/_____/ _____

(dd / mmm / yy)

Name of Investigator / delegate: …….

Signature Investigator / delegate: …….. Date _____/_____/ _____

(dd / mmm / yy)

Name of witness (if applicable): ……

Signature of witness (if applicable): …… Date _____/_____/ _____

(dd / mmm / yy)

A signed copy of this consent form has been given to you to keep for your records and reference.