Effect of Hindmilk on Growth Velocity of Very Preterm Infants

Participant Informed Consent Form
(REB-18-0195)

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UNIVERSITY OF CALGARY

TITLE:

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SPONSOR: Department of Pediatrics Innovation Award Competition

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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

Growth is very important for preterm babies and sometimes they are not able to grow as fast as we would like, this is called extra-uterine growth restriction (EUGR). EUGR has been linked to other conditions preterm babies can develop. Preterm babies are only able to take in small amount of milk so we want to make sure they are getting the most nutrients as possible to help them grow and develop.

Hindmilk, which is the milk collected after the first 3-5 minutes of pumping, is considered a natural way of providing additional calories to preterm babies and has been shown in the past to increase weight gain in preterm babies. Hindmilk is rich in specific fats that are also known to be good for brain and eyes.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to see if feeding babies who have been growing slowly with hindmilk will increase their growth to a healthier rate.

WHAT WOULD MY CHILD HAVE TO DO?

Your baby was born before 32 weeks of gestation and is growing slowly, which is the group of babies who are most likely to benefit from the increased nutrients in hindmilk.

The study will be started when your baby is getting all their feeds orally (or by tube going to his/her stomach). The lactation consultant will teach you how to separate your milk. A 10ml sample of your milk will be sent for testing to measure the fat content.

A few drops of blood will be taken from your baby within 3 days of signing this form and again 2-4 weeks after starting to feed with hindmilk. This sample will only be taken when your baby will already be getting blood tests done so no extra pokes. We will never take a blood sample from your baby if there are no tests ordered for that day.

WHAT ARE THE RISKS?

Blood sampling is done using sterile methods and the risk of infection is extremely low. Samples will be collected at the same time as other tests minimize unnecessary procedures. The amount of blood that will be drawn from your child will be very small (less than $1/25^{th}$ teaspoon) and doesn't put him/her at risk for complications from our study. There are no risks to feeding babies hindmilk.

ARE THERE ANY BENEFITS FOR MY CHILD?

If you agree for your baby to participate in this study, there may be no direct benefits to your baby. However, the study will help us find out if giving hindmilk to preterm babies helps them grow faster and reduce the rate of other complications. The information we get from this study may help us allow other preterm babies to grow and develop at a good rate.

DOES MY CHILD HAVE TO PARTICIPATE?

Your participation in this study is entirely voluntary. You may choose not to participate or you may withdraw from it at any time by contacting the Dr. Belal Alshaikh or any of the other study investigators. You and your baby will continue to receive all the care and treatment without any prejudice. If new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

WHAT ELSE DOES MY CHILD'S PARTICIPATION INVOLVE?

We will 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 (weight, need for oxygen, etc) and course in hospital (medical history, feeding and diet history, medications used, laboratory results, etc).

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

There is no financial cost involved on your part and no financial compensation would be provided for participating in the study.

WILL MY CHILD'S RECORDS BE KEPT PRIVATE?

If you decide to have your baby participate in this research project, your child's medical records will be reviewed by a research assistant or one of the investigators to collect information that will help understand the findings of the study. Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical study records held at Foothills Medical Centre for quality assurance purposes (other relevant organizations may include the Study Sponsor, Health Canada and/or other foreign regulatory agencies). All will have a duty of confidentiality to your child as a research participant, and a duty to observe any applicable data protection laws.

The information gathered on your child will be kept confidential with none of information being released without your expressed 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 study, the results may be published or used for teaching. Nothing that could reveal your child's identity will be included.

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

In the event that you or your child 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. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your child'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 child from the study at any time without jeopardizing their health care. If you have further questions concerning matters related to this research, please contact:

Christel Major (403) 944-3573

or

Dr. Belal Alshaikh (403) 955-2320

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, University of Calgary at 403-220-7990.

Parent/Guardian's Name	Signature and Date
Child's Name	
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.