

Date of document: 10 July 2018

Informed consent form

**Study title: Regular intestinal lavage to promote enteral feeding and prevent necrotizing enterocolitis in extremely preterm infants. A randomized controlled trial.**

## **Background information**

Premature babies have immature bowel function; thus, feeding must be carefully increased after birth. During the time the feedings are increased, the nutrition of the baby is supplemented with extra nutritional liquid, so called parenteral nutrition, that is given through an intravenous catheter (thin flexible tube in a vein). The immature bowel makes it also difficult for the baby to poo, which prolongs the time to accomplish nutrition only through the bowel, so called enteral nutrition. This increases the risk for a severe bowel disease, called necrotizing enterocolitis, that results in severe inflammation of the bowel, eventually leading to surgery and threatening the child's life. Prolonged time to full enteral nutrition leads to longer need for parenteral nutrition and thus intravenous catheter. The longer the intravenous catheter remains in the vein the higher the risk that bacteria will make it in the body and cause infection.

## **What is this study about?**

You are hereby asked if you want to participate in a research study aimed at studying whether regular emptying of bowel content through bowel lavage with sodium chloride can accelerate the nutritional supply of the children through the bowel, thereby counteracting the development of necrotizing enterocolitis or infection. We also intend to study whether this treatment can reduce the risk of other common conditions related to premature birth, such as poor growth, lung disease, etc. All premature babies are routinely monitored on an outpatient basis until the age of 5.5 years, when the child's neurological development is assessed among other parameters. We will therefore also gather this information to study the children's psychomotor development in the long run.

## **What happens during the participation in the study?**

This is a randomized controlled study. The term "randomized" means that participating children are randomly included in one of the study's two groups, the intervention group or the control group. The intervention group includes children who are going to have regular bowel lavage and the control group is the group to which the intervention group is compared, to see whether the treatment is effective or not (hence the term "controlled"). Children to be included in the intervention group will receive colon bowel lavage by means of a thin plastic tube through the rectum twice a day until full nutrition through the bowel has been reached. Children to be included in the control group will be cared for according to the current routine. The care of the children in the two different groups will not differ in any other way than just the bowel lavage. Some previous studies that have examined bowel lavage and / or enema in premature babies

have not shown any side effects. However, we will carefully monitor any side effects and interrupt the intervention if these should occur.

### **Are there any risks with the intervention?**

Theoretically, there is a risk of bowel bleeding, bowel perforation or electrolyte imbalances, i.e. disorder in salt balance. However, similar interventional studies that have been previously conducted have not shown any side effects and bowel lavage is currently used in our department if needed, without any adverse effects noted so far. Nevertheless, the medical staff will carefully monitor for possible side effects and the intervention will be interrupted if they should occur.

### **How does the study affect you?**

If you choose to participate, it means that your child can be included in the study (randomly assigned either to the intervention or the control group). For this, one of the investigators responsible for the study will contact you before or during the first day of the child's birth. All information will be stored, locked and treated confidentially, which means that your or your child's identity will not appear in any prints or in the final scientific presentation. The results will be presented in the form of a scientific article published in a scientific journal for healthcare professionals.

### **Do you want to participate?**

If you want your child to participate in the study, you fill in a form. If you choose to participate, you can cancel the participation whenever you want without having to explain why. If you choose to not participate, you do not need to explain why either. You are welcome to contact the research team directly at the neonatal department, by phone or by e-mail.

### **Protection of personal data**

Responsible for your personal information is Region Uppsala. According to the EU Data Protection Rules, you are entitled to get free of charge all the information about you being handled and, if necessary, get any errors corrected. You may also request that information about you be deleted or that processing of your personal data is limited.

Contact person is ..... Data protection officer is ..... and can be reached by .....  
If you are dissatisfied with the treatment of your personal information, you have the right to send a complaint to the Data Inspection, which is the supervisory authority.

**Information provider:** .....

(fill in the name of the person that provides the information to the guardian(s))

## Informed consent form

Study on regular bowel lavage to promote enteral nutrition and prevent necrotizing enterocolitis in premature babies.

I agree with the information I received and give my consent that my child will participate in this randomized controlled study. I understand that I can interrupt my participation at any time, without justifying why.

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Place	Date
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Signature:

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Name and Surname:

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Mobile number:

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E-mail:

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Signature:

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Name and Surname:

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Mobile number:

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E-mail:

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