GÖTEBORGS UNIVERSITET

Information and invitation to participate in the EPITOP study

Identification of early factors that predict morbidity in premature infants

We would like to ask you if you want your child to participate in a research project. This document provides information about the project and what participation involves.

Background and aim

Being born very prematurely involves care in a neonatal ward. During the care period, the child's condition is monitored by, among other things, taking blood samples. When analyses of these samples are complete, there is a small amount of blood (0.1 ml) left in the sampling tube which is currently discarded. In this project we want to find out whether the leftover samples can be used to examine various substances in the blood (called biomarkers) and see if these can be used for the early detection of those children who are at high risk of various diseases that are linked to premature birth, including the eye disease retinopathy of prematurity (ROP) but also diseases that affect other organs in the body, such as the lungs, intestines, and brain.

Invitation to participate

We are approaching you as you are the responsible parent or guardian of a child born before the 28th week of pregnancy who is being cared for in the neonatal ward at the Queen Silvia Children’s Hospital in Gothenburg.

How is the study carried out?

You will receive a first invitation to participate in the study by a nurse or doctor when your child comes to the ward. We are asking to use blood samples that would otherwise be discarded and to be given access to medical information retrieved from the child's and mother's medical records. We also collect information from national quality registers for newborns (SNQ and SWEDROP).

If you want your child to participate in the study, or just want more information, you can contact researcher Chatarina Löfqvist or the contact person at the department, consultant physician Karin Sävman. If you decide you want your child to participate, you will have to sign a written consent form.

What are the risks?

We use the sample volume that is left over from blood samples taken to monitor and follow up your child's condition. This means that no extra samples are taken from children who participate in the study. The information collected is handled with the same confidentiality as in healthcare.

Are there any benefits?

If you choose to include your child in the study, this will not provide any direct benefits to your child. Hopefully, the results of the study can be used to improve the care of premature babies in the future.

The samples are stored in a biobank

The samples saved in connection with this study will be stored in Biobank Väst (registration number 890 at the Swedish Health and Social Care Inspectorate, IVO), in accordance with the Biobanks in Health Care Act (2002:297), which regulates the manner in which samples may be saved and used, and it also regulates the quality and security of biobanks. This is Västra Götaland Region's joint biobank.

In this study, your child's samples will be stored pending analysis for up to 5 years. Thereafter, the samples will be saved for a maximum of 5 years if you give consent for future research studies, or they will be destroyed if you do not give consent for future studies. The samples will be stored coded, which means that the samples cannot be directly traced to your child as a person. Each sample has a unique code to avoid confusion. The samples and the associated identification list (code key) will be stored at Biobank Väst, separated from each other, and protected from access by unauthorized persons. Coded samples may be made available outside the organization, that is, samples may be analyzed by collaborating partners, industry and pharmaceutical companies within the EU / EEA and/or the USA. They will return or destroy the samples after analysis.

Data management and confidentiality

Data and personal details in the study are handled in accordance with the EU Data Protection Regulation, the General Data Protection Regulation (GDPR), and Regulation (EU) 2016/679 of the European Parliament and of the Council of Europe.

You have the right to request access to your personal data, to have it corrected or deleted, or to have the processing of the data restricted. You also have the right to submit a complaint to the Data Inspectorate (*Datainspektionen*). If you want answers to questions about personal data, you can contact the university's data protection representative, who you can reach via e-mail: dataskydd@gu.se, or telephone: 031-786 00 00.

Coded samples in Biobank 890, the code key, and personal details from register data are stored separately from other data in a locked, fireproof archive for ten years, after which a decision is made on elimination. Your child's results will be processed so that unauthorized persons cannot access them. When the results of the study are presented, in the form of a scientific article, personal details or data that can reveal your identity will not be included.

Participation is voluntary

Your participation is completely voluntary and can be interrupted at any time without the child's care and treatment now or in the future being affected.

How do I get information about the study results?

The results of the study will be presented in scientific journals. You can also contact those responsible for the study to get a summary of the results.

Insurance, compensation

Patient insurance applies to participants in this study. No financial compensation is paid.

Responsible for the study:

If you have further questions, you can contact the following people:

Chatarina Löfqvist: Project manager, senior lecturer, University of Gothenburg
Tel. 0768-672719, Email: chatarina.löfqvist@gu.se

Karin Sävman: Consultant physician, Neonatal Department, Queen Silvia Children's Hospital.
Tel. 031-3434000, Email: karin.savman@pediat.gu.se

Birth age, week + day: ☐ ☐

Informed consent, research study EPITOP

Before you sign, please read the following five statements:

- I have received the written information about the research study EPITOP.
- I give my consent to my child's participation in the study and I understand that participation is entirely voluntary.
- I am aware that I can at any time withdraw my consent and end my child's participation. Stored samples will then be destroyed.
- I agree to the principal investigator or a study monitor having access to the mother's and child's medical records and the relevant register records, to the registration of personal data, and to the electronic storage and management of collected data in a coded format.
- I consent to the samples being stored in the biobank and used for the research purposes described in the information. Yes ☐ No ☐

Consent, preservation of samples for future research studies:

- Samples can be valuable for as yet unplanned research projects (as described in the information) if you give your approval to saving them for this purpose. In these cases, a new ethical review will take place and you may be contacted again with a request. Do you agree that any samples left after the EPITOP study can be saved in a biobank for future research projects that are not described here but which, if applicable, will be reviewed and approved by the Ethical Review Authority?

Yes ☐ No ☐

Child's personal identity number (*personnummer*) and name:

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Relation to the child:

Signature	Name	Date
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Relation to the child:

Signature	Name	Date
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Clinician's signature

I confirm that I have given both verbal and written information about the described study and that a copy of the information for research participants has been given to the parent or guardian.

Signature	Name	Date
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