Research information

GÖTEBORGS UNIVERSITET

Information and enquiry regarding participation in the VEGF study

Investigation to examine whether a drug (anti-VEGF) injected locally into the eye passes into the bloodstream

We would like to ask you if you would consent to your child taking part in a research project. This document contains information about the project and what participation would involve.

Background and purpose

Many premature babies run the risk of developing the eye disorder retinopathy of prematurity (ROP). To identify ROP that requires treatment, a large number of premature babies undergo eye examinations. Although the standard treatment in the past has been laser therapy, the use of medication has emerged in recent years. Medication takes the form of an intravitreal injection in order to slow down the pathological progression of this retinal disorder. There are several different anti-VEGF molecules available, including ranibizumab (Lucentis®) and bevacizumab (Avastin®). The aim of the treatment is to bind a vascular growth factor known as VEGF.

Studies have shown that different types of anti-VEGF molecules bind to VEGF in different ways. The focus has been on examining VEGF levels and injected anti-VEGF in the circulatory system to determine whether a drug injected locally into the eye passes into the bloodstream. Studies have shown that treatment with bevacizumab reduces VEGF levels in both serum and plasma for weeks and up to months following treatment. In the case of ranibizumab, the results are contradictory with regard to VEGF levels in serum and plasma following injection of the drug. Our aim in this project is to investigate the best way of measuring anti-VEGF and VEGF levels following injection into the eye.

Enquiry regarding participation

We are contacting you as a responsible parent/guardian of a child who was born before the 31st week of pregnancy and who will receive anti-VEGF treatment for severe ROP.

What form will the study take?

The reason why you have received an initial invitation from an eye specialist to participate in the study is that your child is scheduled for anti-VEGF treatment.

If you would like your child to participate, extra blood and urine samples will be taken before the injection and also 24 hours, 4 days, 2½ weeks, and 12 weeks after treatment.

If you would like your child to participate in the study, or if you would like more information, you can contact researcher Ann Hellström. If you decide to participate, you will be required to sign a written consent form.

What are the risks?

As part of the study, two extra vials of venous blood will be taken on each occasion, i.e. 0.5 mL of blood each time (equivalent to ⅒ of a teaspoon), making 3 mL in total. Venous sampling can cause the child discomfort and pain. To ease the pain, an analgesic gel will be applied before the sample is taken. A urine sample is taken via an absorbent diaper insert. It does not cause the child any discomfort.

Are there any benefits?

If you agree to your child's participation in the study it will not benefit them directly. Hopefully, the results of the study can be used to provide care and treatment of premature babies in the future.

The samples are stored in a biobank

The samples in this study will be stored in Biobank West (registration number 890 at the Health and Social Care Inspectorate) in compliance with the Biobanks in Medical Care Act (2002:297), which regulates the manner in which samples are permitted to be stored and used as well as the quality and safety of biobanks. Biobank West is the joint biobank for Region Västra Götaland. Your samples in this study will be stored pending analysis for up to 5 years. After that, the samples will be stored for a further 5 years (possibly less) if you grant consent for their use in future research studies. If you do not grant consent for their use in future research studies, the samples will be destroyed. The samples will be marked with a code, which means they cannot be traced back to your child. Each sample is given a unique code to avoid any mix-up. The samples and the identification list (code key) will be stored separately from each other and will be protected against unauthorised access. Coded samples could be made available to parties other than the principal, i.e. samples could be analysed by partners, industrial enterprises, and pharmaceutical companies within the EU/EEA and/or the USA. The samples will be returned or destroyed following analysis.

Data processing and confidentiality

Personal data and other data that emerges within the framework of the study are processed in accordance with the EU General Data Protection Regulation (GDPR) and the Regulation (EU) 2016/679 of the European Parliament and the Council. You are entitled to access your personal data, to have your data corrected or erased, or request that processing of your data be limited. You also have the right to file a complaint with the Authority for Privacy Protection. If you have any questions regarding personal data you can contact the University's data protection officer by email at dataskydd@gu.se, or by telephone on 031-786 00 00. Coded samples in Biobank 890, the code list, and personal data from the register are filed separately from the study data in locked, fire-protected security archives for 10 years, after which a sorting decision is made. Your responses and results will be processed in a way that they cannot be accessed by unauthorised persons. When the results of the study are presented in the form of a scientific article, no study data or personal data will appear that could reveal your identity.

Voluntary participation

Your participation is entirely voluntary and can be discontinued at any time without this affecting your child's current or future care and treatment.

How can I gain access to the study results?

The results of the study will be presented in scientific journals. You can also contact those responsible for the study if you would like a summary of the results.

Insurance, payment

Participation in the study is covered by the Patient Insurance Scheme. No payment is made.

Person responsible for the study

If you have any further questions you can contact Ann Hellström, Professor, Consultant, Department of Paediatric Opthalmology, Queen Silvia Hospital for Children and Young People. Tel. 031-3434000. Email: ann.hellstrom@medfak.gu.se

Informed consent, anti-VEGF research study

Before you sign, please read the following five points

- I have read the written information about the anti-VEGF research study.
- I consent to my child's participation in the study and I am aware that participation is entirely voluntary.
- I am aware that I can at any time and without any explanation withdraw my consent and conclude my child's participation. Samples in storage will then be disposed of.
- I consent to the person responsible for the study or a study monitor accessing both the mother's and the child's records as well as relevant register data; to the registration of personal data; and to the storage and electronic processing of collected data in coded form.
- I consent to the samples being stored in a biobank and used for the research purposes set out in the information provided.

Child's civil registration number and name

_____

Relationship to the child:

Signature Name in block letters Date

_____ _____ _____

Relationship to the child:

Signature Name in block letters Date

_____ _____ _____