Invitation to participate in this study

Study title: "Effect of fetal aortic valvuloplasty on outcomes. A prospective observational cohort study with a comparison cohort."

Summary

The purpose of this study is to investigate whether it is possible to improve the outcomes for children with aortic stenosis (aortic valve obstruction and left-sided heart under-development) by performing aortic balloon valvuloplasty (a balloon dilation of the aortic valve) during pregnancy.

Background and purpose

Heart defects can be detected during the routine fetal ultrasound examination performed at 18-20 weeks of pregnancy or later. If a fetal heart has aortic stenosis (obstruction of the aortic valve), we know this may lead to reduced growth of the left-sided chambers (left atrium and left ventricle) of the heart. After delivery, newborns with a smaller left-side of the heart may have worse heart function and a greater risk of not surviving after cardiac surgery.

Some fetal therapy centres in Europe and the United States offer a pre-natal treatment to dilate the obstructed aortic valve with a tiny balloon, known as aortic balloon valvuloplasty. Previous research has shown the benefits of this treatment include increased blood flow through the left side of the heart and improved heart function during the remainder of the pregnancy, which is thought to provide an opportunity for a better postnatal outcome.

Although this treatment has been offered for many years, there is no prospective study that compares the outcomes of children with the same heart defect undergoing fetal treatment with those not treated until after birth. Therefore, we do not know if this fetal treatment really confers benefit or not. This study aims to find out whether aortic balloon dilation during fetal life leads to better outcomes for a child with aortic stenosis.

Request for consent

Your fetus has been diagnosed with aortic stenosis and we are asking for your consent to participate in this study.

How is the study performed?

If you choose to participate in the study, we will monitor fetal cardiac growth and function of your baby using ultrasound during pregnancy until 2-3 weeks before term. The number of examinations will not be different from the number of examinations we will recommend if you decide not to participate in the study. After delivery we will continue to monitor your child until about two years of age.

Your participation in the study will not affect the treatment you and your baby receive during pregnancy, nor how your child will be examined or treated after birth.

If you decide to participate, the results of the ultrasound studies of your fetus and your child will be recorded in the study database and anonymised before analysis and the results of the study are published. The study is a European collaboration and the anonymised results of the examinations of your fetus and child may be sent abroad for analysis.

What are the risks?

Participation in the study does not involve any risks.

Are there any benefits?

Participation in the study does not bring any benefits to you or your fetus / child. This study will provide information for future counselling and treatment.

Data handling and privacy?

All data from the study will be stored in a register and computerized in such a way that unauthorized persons cannot share them (anonymised). This ensures that the registry will be saved and administered in such a way that you and your child's name and social security number cannot be distinguished. Your identities are replaced by code numbers. The data and code list are kept separately and will be kept for at least 10 years. Only those who are responsible for the study have access to the code key. Encoded data may be sent to employees at universities in another European country. When data from the study is eventually published in a scientific journal, it will not be

possible to identify any individual fetus or child. The Board of Sahlgrenska University Hospital is responsible for the processing of personal data. According to the Personal Data Act (1998: 204) you have the right to apply for information about which personal data are processed and to request a registry extract. You are also entitled to request modification of any incorrect information. The Personal Data Ombudsman is the person responsible for processing your personal information in a lawful and correct manner. If necessary, the Personal Data Ombudsman can help you to get information about what has been registered and get any corrections made. The Personal Data Ombudsman can be reached at the following address (see Persons responsible for the study).

How do I get information about the results of the study?

A summary of all data from this study will be published in a medical journal. The study will last for several years so it can take a long time before the results are complete. If you wish, we will send the scientific report to you. If you want to meet us to explain the results, this is also possible. You should then contact one of the persons responsible for the study (see below). You can also choose to completely avoid all information about the study results.

Insurance and compensation

Patient injury insurance applies. No financial compensation is paid for participation or for lost income. Participation is voluntary and you can cancel participation without explanation at any time and without affecting your or your fetus' / child's continued treatment and care. You can, if you choose to cancel participation, also request that all data from your fetus and from your child be deleted from the research database. If you want to withdraw your consent to participate in the study, please contact the principal investigator (see below).

Responsible for this research: Västra Götaland Region, Norra Hamngatan 14, 41114 Göteborg

Principal investigator: Mats Mellander, Associate Professor, Senior Physician, Children's Heart Unit, Queen Silvia's Children's Hospital, mats.mellander@vgregion.se, phone 031-3434659

Personal data ombudsman: Västra Götaland Region, Sahlgrenska University Hospital, 413 45 Göteborg, phone 031-343 27 15.

Consent Form

For participation in the study: "**Outcomes of balloon dilation for fetal aortic stenosis: a prospective, non-randomized, controlled multicenter study**"

I have been informed of the study and how personal data will be processed, and I have had the opportunity to ask questions and have had them answered and I agree to participate in the study. (city, name and date)

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