Participant information to pregnant women with diabetes

Copenhagen Baby Heart Impact

Routine heartscan of newborns with diabetic mothers, with follow-up of the child through early childhood

Offer for all pregnant with diabetes,
who give birth in Greater Copenhagen until 2021

We want to ask you whether you are willing to consent to your child's participation in a scientific research study undertaken by cardiologists and obstetricians. Before you give your consent, you must fully understand what the study entails and why it is being conducted. Therefore, we ask that you read this information leaflet carefully. If you need further clarification, we offer to answer, in person, whatever questions you may have to this leaflet and the study in particular. You are welcome to bring a family member, a friend or acquaintance when you come and see us.

If you decide to give your consent, you will be asked to sign a consent form. Please note that you are entitled to some time to consider whether or not to sign the consent form.
Participation in the study is voluntary. You may at any time and without stating any reason withdraw your consent. This will not affect any treatment you child may be undergoing.

Why do we offer some children from Copenhagen Baby Heart a follow-up heart scan?

The most common congenital disease is a heart defect. In Denmark, approx. 450 babies are born every year with a heart defect. The defect appears as the foetus develops, and in most cases the reason is not known. The most common heart defects are holes in the walls separating the heart chambers and defects in the development of the heart's blood vessels or valves.

Approx. 70% of children born with a heart defect require some kind of treatment at some point, whereas the rest will do fine without treatment or only regular check-ups. At the time of writing, approx. 22,000 Danes live with a congenital heart disease.
The most serious heart defects in newborns will have been detected during pregnancy. Less serious heart defects and in rare cases serious heart defects cannot always be detected during pregnancy. This may be explained by the fact that scanning of the foetus is technically more difficult than scanning a newborn.

An ultrasound scan is an effective and safe method of examining the heart and therefore very suitable for diagnosing possible heart defects in newborns. If we detect a heart defect, we make sure that the appropriate control and treatment, if necessary, are started as soon as possible. In doing so, we expect to be able to limit or possibly totally eliminate any later consequences of the heart defect thus giving the child the best possible conditions for the future. Findings that require future visits with a paediatrician will be noted in the child's medical records.

Diabetes – types 1 and 2 as well as gestational diabetes – may affect the development of the foetus, and in children of diabetic mothers we see a higher than normal incidence of heart malformations. The risk, however, is very limited if the diabetes is well controlled. Up to 3 % of all pregnant women show signs of diabetes which is therefore one of the most common complications seen during pregnancy in Denmark.

Why are we interested in children born to diabetic mothers?
Previous studies of the hearts of babies born to diabetic mothers have included very small groups of children. As opposed to this current research study, those studies did not systematically look at healthy children but rather children showing symptoms.

The purpose of this study, therefore, is to acquire greater insight into exactly how many children of diabetic mothers are born with a heart disease and to clarify any benefits to the child of a thorough heart scan immediately after birth. The long-term follow-up of the results will allow researchers to shed further light on many new and yet undisclosed conditions relating to the development of these children. In practice, this means that we offer to scan your child's heart a maximum of three more times between now and the time your child turns 10 years old. The information gathered will help improve the future treatment of children born to diabetic mothers as well as the advice given to diabetic pregnant women.

Heart scan (echocardiography) and biobank of babies born to diabetic mothers

All women who have diabetes types 1 or 2 or develop gestational diabetes (diabetes developed during pregnancy), and who give birth in Copenhagen will be offered an ultrasound scan (echocardiography) of their baby's heart. The echo test will be performed within the first four weeks of birth. An estimated total of 1400 newborns will participate in the study. We may at some later date contact you to inquire whether you would be interested in participating in further tests.

The ultrasound scan will be performed by an ultrasound technician or a doctor with Hjertesygdomme Forskning 2, Herlev Hospital. Your child will be scanned on the chest near the heart, and therefore all clothes must be removed from the upper body. Six sensors will be attached to your child's upper body to measure your child's heart rate during the scan, and a device will be placed around a hand/foot to measure blood oxygen levels. A blood pressure cuff (a cuff with an inflatable balloon connected to a gauge) will be placed on your child's upper arm to measure his/her blood pressure. The actual scan takes approx. 10 minutes. It is important that you are present during the examination. Please note that if you agree to participate in the study, you also agree to receive information about any findings, including abnormal findings. The offer of an ultrasound scan made to pregnant women remains valid for a period of two years, until the end of 2021.

The ultrasound scan of your child's heart is normal

If the ultrasound scan shows a normal heart, you will be notified right away.

If the ultrasound scan of your child's heart is not normal

If there is even the slightest doubt that the scan is normal, it will be reviewed by a cardiologist. In this case, you will be notified that within a couple of days you will be contacted by a cardiologist who will explain the scan to you in

more detail. If suspicion of a heart defect persists, you and your child will be offered an additional scan and additional information. If the heart defect is confirmed, you will be referred to the children's outpatient cardiology clinic for further evaluation. In some cases, an ultrasound scan of the heart may reveal other diseases. If this is the case, we will refer your child to further evaluation by the relevant specialists. Information relating to such future examinations will be registered in the project on an ongoing basis.

Offer of follow-up heart scan

At present we do not know much about the long-term effects on the baby's heart function of conditions that adversely affect the mother's health, such as diabetes during pregnancy. In some cases, therefore, we will offer one or more control scans as part of our research study throughout the child's early adolescence. This will offer us greater insight into the impact of diabetes on the child's heart, not only at the time of birth but also later in life. The number of additional scans will not exceed three until your child turns 10 years old.

Who can participate?

You can participate if you are pregnant and have diabetes type 1 or 2 or have currently been diagnosed with gestational diabetes. Your prenatal care must be provided by Rigshospitalet, Herlev Hospital or Hvidovre Hospital.

Pros and cons

The pros of this study are that we will obtain significant insight into the frequency and importance of heart defects in babies born to diabetic mothers. Furthermore, it will be possible to diagnose and, where relevant, treat a heart defect before any unnecessary complications develop. There is no risk involved, and the only inconvenience is the time spent on having the scan performed. In addition, your child may be diagnosed with an insignificant heart defect or a defect that will not require any follow-up and treatment until he/she is an adult. In that case, the result of the scan may cause unnecessary concern.

Time and place

The actual scan is performed at Hjertesygdomme Forskning 2, Herlev Hospital between 8 am and 5 pm. The examination takes a total of 30 minutes. Once an appointment has been made with the project coordinator, you will be notified electronically of time and place.

Registering as a participant and scheduling of appointment

You can sign up as a participant in one of the following ways:

- At the actual examination.
- By signing and emailing the enclosed form to: hgh-babyheart@regionh.dk
- By signing and mailing the enclosed form to: Copenhagen Baby Heart, Hjertesygdomme Forskning 2 S104, Herlev Hospital, Borgmester Ib Juuls vej 1, 2730 Herlev.

Communication of medical record information

When giving your written consent to your child's participation in the Copenhagen Baby Heart Study - Impact, you agree that the project is given direct access to relevant health information in the medical journal in order to conduct, monitor and control the trial. Necessary information from the mother's and child's medical records will be communicated to the responsible doctors such as data relating to pregnancy, hereditary deceases and delivery. As regards new-borns with heart decease, information included in the medical records will be communicated on a continuous basis.

Data are collected for scientific medical purposes in order to investigate the natural history and prognosis of congenital deceases. Personal data will be treated as strictly confidential and will always be handled in accordance with relevant confidentiality standards as well as all

regulations relating to the processing of personal data and the protection of personal privacy.

Data will be protected in accordance with current applicable laws on the processing of personal data and the Danish Health Act.
When giving your written consent to your child's participation in the study, you simultaneously consent to data being obtained from the mother's and child's medical records as described above.

Financial aspects

In 2019, the Capital Region of Denmark Research Foundation has granted Copenhagen Baby Heart Impact DKK 2,500,000. The projects, however, is not fully financed, and additional funding is continuously sought from various sources. None of the participating doctors have any financial interest in the project. The Danish National Committee on Health Research Ethics will be informed about future funding entities.

Research subject compensation

Research subjects are not compensated.

Principal investigators

The principal investigators are Dr. Kasper Iversen, professor, senior consultant and Doctor of Medical Science as well as Dr. Henning Bundgaard, professor, senior consultant and Doctor of Medical Science.

Access to study results

The results of the study will be published continuously in international journals. The data collected may be put to scientific use for many years to come, i.e. also after your child has become an adult.

Where can I obtain additional information?

If you want to find out more about the study or have questions, please feel free to contact research secretary Pia Dupont, Department of Cardiology, Herlev Hospital, Borgmester Ib Juuls vej 1, 2730 Herlev.

Contact details:

- **Telephone: 3868 6405**
- **Email:** hgh-babyheart@regionh.dk

We hope that this information leaflet provides sufficient insight into what it means to participate in the study, and that you will be well prepared to make the decision on whether or not to consent to your child's participation.

Thank you

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