IMPACT

STUDY FOR IMPROVING MATERNAL, PREGNANCY AND CHILD OUTCOMES

Participant Information

National Director of Studies
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Introduction

We are asking you to participate in a study designed to investigate whether conditions in early pregnancy can predict which women are likely to suffer complications later in pregnancy. All women who have an ultrasound performed early on in their pregnancy are asked to participate. Initially, the study will focus on pre-eclampsia, but at a later stage the focus will also turn to other complications, such as small for gestational age babies (babies that are small in size relative to the number of weeks into the pregnancy) and premature birth.

Your participation in the IMPACT study is strictly voluntary, and you may decide to stop participating in the study at any time. Your medical care will not be affected in any way should you choose to participate in the study. The study will be conducted at several gynaecology clinics across Sweden.

About the study

The three most common severe complications encountered in the late stages of pregnancy are pre-eclampsia, small for gestational age babies and premature birth. These three complications may lead to morbidity (susceptibility to disease), and in rare cases, to the death of a newborn, while pre-eclampsia is one of the most common causes of acute illness in expecting mothers. It is very difficult to determine early on in pregnancy which women are likely to develop these complications. The purpose of this study is to develop an effective screening test that can be used to determine whether an individual has a high risk or low risk for these complications so that successive treatment can be tailored to address this risk and preventative measures can be taken if necessary

Check-ups in weeks 11-14

In connection with your first routine ultrasound or combined ultrasound and biochemistry (CUB) examination in weeks 11-14 of your pregnancy, you will be informed about the study, and if you do decide to participate, you will be registered as a participant in the IMPACT study. You will be asked to sign a consent form indicating that you wish to participate, which will be followed up by a doctor, midwife or assistant nurse asking you series of questions about your lifestyle and your pregnancy. Your blood pressure, height and weight will be recorded and a blood sample will be drawn, one tube holding a maximum of 10 ml (in some cases a frozen blood sample from KUB may be used instead). This will add about 20 extra minutes to your visit. At the time of the ultrasound examination, some clinics will use Doppler ultrasound to examine the blood flow in the artery that leads to the uterus.

Biobank (extra blood samples)

Some of the hospitals participating in this study have access to a biobank. If you receive your care at one of these hospitals, additional blood samples (2 x 10ml. tubes and 1 x 5ml.) may be drawn and frozen at a biobank connected to the hospital. For your reference, the biobank currently being used is called Uppsala

biobank. The biobank's contact information is: *http://www.uppsalabiobank.uu.se/sv, Uppsala Biobank Dag Hammarskjölds väg 38, 5 tr UCR, Uppsala Science Park, Hubben 751 85 Uppsala, info@uppsalabiobank.se.* All of your information and all samples are coded and handled anonymously. In the future, researchers will, after obtaining the approval of the ethics committee, be permitted to apply to the study's research committee to gain access to the remaining blood samples in the biobank. This is for related research intended to detect valuable markers for pregnancy complications. It will not be possible to identify you as an individual if you have submitted blood samples as only coded data will be released.

Benefits, risks and safety
Participation in the study will not provide you with any benefits related to your pregnancy but will provide a benefit to the next generation of women in Sweden during their pregnancies. You may also directly benefit from the study during a future pregnancy. Blood sampling may be unpleasant for some participants and may result in minor bruising.

Participation
If you decide to participate in the study, you are free to withdraw from the study at any time, without having to provide a reason, and this will not have any effect on your general health care. At any time, you may request to have your blood samples returned (which are then destroyed) as well as any personal information or information about your pregnancy.

General
For more information on the study, refer to the chief researcher at your hospital (see the address information below). You are not required to respond to all of the questions asked during the initial interview and you may decide to end the interview at any time.

Processing of personal data
The personal data controller for your personal data is Uppsala University. The completed study will not identify individual participants. Data pairing, pregnancy outcomes and blood samples are performed by The Swedish Pregnancy Register, and researchers accessing the data afterwards will only have access to coded data. Reporting is only done at the group level. The only individuals permitted to work with uncoded data are the study administrators at your local hospital and The Swedish Pregnancy Register in order to perform quality assurance and to supplement information about your pregnancy, delivery or newborn. Personal data is handled in accordance with the new EU General Data Protection Regulation (GDPR). You have the right to submit an application to request information about what personal data is being processed. You can submit your application to The Data Protection Representative (region.uppsala@regionuppsala.se). Your responses and information will be processed in such a way that unauthorised persons will not have access.

Biobank samples
Samples taken during the study will be submitted to Uppsala biobank (registration number 827 at the Swedish Health and Social Care Inspectorate [IVO]) in accordance with The Swedish Biobanks in Medical Care Act (SFS 2002:297), which regulates the ways in which samples can be saved and used. The samples will be coded for storage which means that the samples can not be connected directly to you as an individual. Each sample is given a unique code to avoid any confusion. The samples and the connected

identification list (code key) will be stored separate from each other at Uppsala biobank and will be protected to prevent access by unauthorized individuals. The code key will be provided to the study administrators and The Swedish Pregnancy Register. Researchers will be able to access our biobank with its connected pregnancy data after being granted ethics approval for their projects. Your blood samples may be sent to our laboratory for analysis or to one of our partners' laboratories, either inside or outside the EU/EEA and the US. Proteins, hormones and genes may be analysed. Similarly, any future illness that you or your child experiences may be studied via a follow up in the national health and quality register. If a researcher wishes to follow up via the health and quality register, data will be handled by the Swedish Pregnancy Register and the respective authority. Researchers are only granted access to anonymised data. You have the right, without being required to provide further explanation, to have your blood samples destroyed and your data deleted.

Results
The study results will be published in medical journals and will be available for review on the IMPACT study's website. It will not be possible to view your individual results.

Approval
The study has received the approval of the Regional Ethical Review Board in Uppsala.

Before deciding whether to participate, it is important that you understand what the study means for you. If you have any further questions or would like more information please refer to your healthcare provider or any of the contact persons listed below. If you choose to participate in the study, we will ask you to sign the "Informed Consent", which you will be provided a copy of.

Responsible party (for local patient information, the primary responsible party and the local responsible party/parties will be registered)

Primary responsible party and local responsible party in Uppsala:
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Local responsible party Gothenburg:
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Local responsible party at Skåne University Hospital:

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Local responsible party Stockholm:

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