PREDICTION OF PREGNANCY COMPLICATIONS

WELCOME TO OUR UNIT
We would like to invite you to take part in a research study. Before you decide whether to do so it is important for you to understand why the research is being done and what it will involve.
Please take time to read this leaflet. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this. Professor Kypros Nicolaides

RESEARCH STUDY
PREDICTION OF PREGNANCY COMPLICATIONS

We are looking for new ways through scientific research to improve the care of pregnant women and their unborn babies. As part of this work, we are inviting all women that attend our unit for their routine scans (11-13 and 19-23 weeks for singleton and twin pregnancies, 30-33 weeks for twins and 35-37 for singletons) to participate in a large study on detection and prediction of pregnancy complications such as preeclampsia (high blood pressure of pregnancy) and premature birth.

Pre-eclampsia and premature birth are two important complications of pregnancy which can have serious implications for mother and baby. These problems can affect any pregnant woman, irrespective of previous healthy pregnancies and irrespective of how healthy the mother is.
Our aim is to try and identify the women who are at high risk of developing such pregnancy complications and to do so as early in pregnancy as possible.
Routine care

Each visit at 11-13, 19-23, 30-33, and 35-37weeks will include:

- Ultrasound examination of the fetus to diagnose major abnormalities and to assess blood flow to the uterus and placenta.
- Measurement of your weight, height and blood pressure.

The visit at 11-13 weeks will also include assessment of your chances for having a baby with Down's syndrome and other chromosomal defects from ultrasound markers and a blood test. The visit at 19- 23 weeks will also include measurement of the length of the cervix (neck of the womb). The visit at 30-33 or 35-37 weeks will also include ultrasound examination of blood flow in the cord and vessels of the baby to assess fetal well-being.

What will happen to me if I take part in the research study?

This will involve the following:

- Saving some of the blood that we take routinely from you to determine the chance for Down's syndrome at 11-13 weeks. We will also collect a blood sample at 19-23, and 30-33 weeks for twins and 35-37 weeks for singletons. These samples will be coded and stored for analysis including in the future, after the end of your pregnancy. The results will not affect the management of your pregnancy.
- Your coded samples maybe transferred to other institutes or collaborators in the UK or abroad for analysis.
- Analysis of your blood coded sample may involve that of your DNA, which gives information on your genetic profile. This could include the whole sequence of your genome, your body's 'instruction manual' that contains the information needed to make you, run you and repair you.
- Your data collected during the study and sections of your medical notes relevant to the research, may be looked at by individuals from the NHS Trust or from regulatory authorities.
- With your permission, we will collect your health data (before, during and beyond your pregnancy) from the NHS or other organisations. The collection of health data may continue for your lifetime and beyond by academic and or industrial partners. We might also contact you for additional information.
- To collate your medical history records from other organisations we will need to provide basic identifiers such as your name, date of birth, post code and NHS number with your prior permission.
- Your data will not be shared with personal insurers and marketing companies, but may be shared with other institutes or collaborators in the UK or abroad for research purposes. However, to maintain your privacy, information that could identify you will be removed from your data, meaning that researchers cannot see this information. They will only have access to your de-identified genomic and health data.
- King's College Hospital, which is the study Sponsor, will take all reasonable steps to ensure that you data will always be stored securely.

Why have I been chosen?

All pregnant women attending our unit for their scans are welcome to take part in this study.

Do I have to take part?

It is up to you to decide whether you would like to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. Once you have decided to take part you are still free to withdraw at any time without giving any reason and any data or blood samples collected will be discarded.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What are the possible benefits of taking part?

The information from analysis of the coded samples will have no direct benefit to your current pregnancy. The information we get from the study may help us to help you and/or other women in the future.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks to you or your baby from allowing us to store some of the blood sample we collect.

Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential.

What if I want to complain?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [see below]. If you remain unhappy and wish to complain formally, you can contact the Patient Advice and Liaison Service (PALS) at 02032993601 or email kch- tr.PALS@nhs.net.

What will happen to the results of the research study?

The results will be published in medical journals and perhaps also in the press. You may request a copy of any published documents in relation to the study. You will not be identified in any of these reports.

Who is organising and funding the research?

This research is carried out by the team of Professor Kypros Nicolaides and it is funded by the Fetal Medicine Foundation (UK registered charity).

The London - Dulwich Committee has reviewed and approved the study.

Contact for further information

Please email Dr Argyro Syngelaki on argyro.syngelaki@nhs.net