What are the side-effects of taking part?
Some women can find high vaginal swabs uncomfortable. Taking part may increase the time you need to spend in the clinic. Blood samples will be taken that are not related to your routine care. They are associated with momentary discomfort and occasionally bruising . The dental examination may be associated with very mild discomfort.

What happens if anything goes wrong?
In the unlikely event that you are harmed by taking part in this study no special insurance applies. However, if you are harmed due to negligence normal NHS indemnity may apply, but you may have to pay for this action. Regardless of this, should you wish to complain about any aspect of the way you have been approached or treated during the course of this study the normal NHS complaints mechanism is available to you.

What drug is being tested?
There is no drug being tested.

What will happen to my sample?
Samples will be frozen and stored in freezers at St Thomas' Hospital, London. We will measure substances in the samples to pick up differences between women who have their babies early and women who do not. No one will be able to identify you from the samples. Fetal fibronectin samples are analysed immediately and then discarded (they are not stored).

What will happen to the results of the study?
The results will be published in medical journals. You will not be identified in any report/ publication

Who is paying for this research?
Tommy's Charity and the National Institute for Health Research (NIHR) has funded this study.

Who has reviewed this study?
NRES Committee London - City & East reviewed and agreed this study.

What do I do if I have further questions or want to take part?
For further information please contact:

Natasha Hezelgrave
Clinical Research Fellow
tel: 020 7188 3639

or

Annette Briley
Clinical Trial Manager
tel: 020 7188 3643

Thank you
for taking time to read this leaflet
and considering taking part
in this study. You will be given a copy
of this leaflet and signed consent form
to keep if you choose to participate

Guy's and St Thomas' NHS
NHS Foundation Trust

INSIGHT

Biomarkers in Preterm Birth

Predictive Markers for Preterm Labour

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and family if you wish. Please ask if anything is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Patient Information Sheet Version 2 (23/4/13)

Background

Babies born very early are more likely to have health problems than babies born at the right time. Although many do survive, being born early may affect them throughout their life.

Doctors have done a lot of work to try and stop babies being born too soon, but they still cannot accurately predict which women will have their baby early. We carried out a small study to measure a biomarker called 'elafin' in vaginal fluid. We found in women who had their babies early (less than 37 weeks) there was more elafin in the fluid than we would expect.

We would like to investigate this further to make sure this test works. We need to look at this substance in vaginal fluid in a much larger group of pregnant women. We also want to measure other natural substances in vaginal fluid, in saliva and blood , for example, markers of infection or inflammation, which may be important in predicting preterm birth. We would also like to see if there is a link between dental (gum) disease and preterm birth.

In order to give the best chance of predicting early birth, we would like to collect at least one sample of vaginal secretions via a speculum exam (like a smear) between 10 and 18 weeks' gestation from women at risk of preterm birth, and also later in the pregnancy before 28 weeks, as well as other samples of your saliva, and a blood test from your arm.

Currently, some women thought to be at high risk of having an early baby are offered a fetal fibronectin test. This involves the doctor or midwife doing a speculum examination and taking a high vaginal swab to look for a special substance, called fetal fibronectin, that may predict an early birth. This test has been used in research into preterm birth for more than 15 years.

Women at high risk of premature birth would be routinely offered this swab test, as well as an internal ultrasound scan to look at the length of the cervix. If you are offered this, we can take the swab test for the other substance 'elafin' at the same time, so you don't need to have another speculum examination. We will then compare both tests to see if we can accurately predict who will go into labour early. We may also ask if a sample can be kept to measure other substances, e.g. markers of infection or inflammation, that may help us to predict preterm birth in the future. You will also be asked if you will agree to having a blood test which will be stored for genetic analysis to see if we can identify women more likely to have an early baby. We may ask you if you would be willing to have an oral (dental) examination later in your pregnancy.

Why have I been chosen?

You have been asked to take part because you are pregnant and have either delivered early before or had an operation on your cervix (neck of the womb). This may mean that you are at higher than average risk of a preterm delivery.

What do I have to do if I take part?

You will be seen by a research midwife who will answer any questions you may have. Once you have agreed to take part you will be asked to sign a consent form and given a copy of this to keep.

The midwife will ask you about your past medical & obstetric history, and ask you to produce a sample of saliva, and will take a blood test when you are between 10 and 32 weeks pregnant. The speculum (with up to 3 swabs taken) will be taken at the same visit by either the research midwife or doctor together with an internal ultrasound if clinically useful.

If you are willing, and if you have further appointments to monitor your risk of early birth, you will be asked to provide another blood, saliva and vaginal fluid sample on each occasion (usually 2-4 visits). The doctors looking after you will know the result of the fetal Fibronectin swab within 30 minutes and will discuss this with you. Your usual antenatal care will continue and you will be seen by your normal doctors and midwives.

We will find out what happened to you and your baby through the hospital medical records and your hand held notes. The dental examination will take about 5 minutes and involves looking at your teeth and gums.

Will my taking part be kept confidential?

All information stored about you will have your name, address and other identifying details removed. No one will be able to identify you from anything we record. All computers used will be password protected. Only people directly involved in the study will have access to the information.

Do I have to take part?

Whether you decide to take part or not is entirely up to you. Your decision will not affect the care you receive in any way. If you agree to take part, you are free to withdraw at a later stage, without giving a reason, although you may be asked if you mind us collecting details about your delivery from your medical notes. Again it is entirely up to you if you agree to this.

What are the benefits of taking part?

You may not benefit personally from taking part, but you may help us develop a screening test that helps women in the future. The extra information the doctors looking after you get from the fetal Fibronectin test may change your antenatal care but the results from the elafin test will not affect your antenatal care.