INSERT LOCAL DETAILS HERE

QUIDS Study

Quantitative Fibronectin to help Decision-making in women with Symptoms of Preterm Labour.

Participant Information Leaflet

You are being invited to take part in a research study. Before you decide whether or not to take part, 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. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

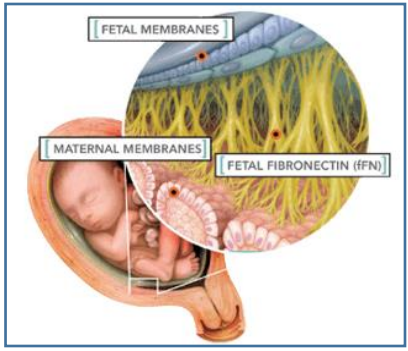
Preterm labour is when labour starts before 37 weeks of pregnancy. Diagnosing preterm labour is difficult and most women who have signs of preterm labour are still pregnant a week later. This means that some women may receive treatment or care that is not helpful to them if they do not give birth following signs of preterm labour. Possible treatments include steroids, magnesium sulphate and transfer of the mother to another unit – all of these being stressful and costly.

A test called fetal Fibronectin (fFN) may help to improve the diagnosis of preterm labour. The test involves the measurement of fFN in a swab taken at speculum examination (like a smear test), and is part of the usual care offered to a woman presenting with potential signs and symptoms of preterm labour.

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

This study aims to look at the results of the fetal fibronectin test obtained from women who are showing signs of pre-term labour and when they give birth. The information gathered will be used to develop a tool that will help doctors interpret tests such as fFN and ultrasound scans, allowing doctors to decide how best to care for women who may give birth to their babies early.

What is fetal Fibronectin?



Fetal fibronectin (also known as fFN) is a protein that is produced by your baby and is found where the fetal sac and the lining of the womb meet. Its purpose is to hold your baby close to the wall of your womb.

In a normal full-term pregnancy, fetal fibronectin begins to break down naturally, and is detectable around week 35. If your body is getting ready to give birth prematurely, fFN may be detected before week 35.

Why have I been asked to take part?

You have been asked to take part because you are between 22 and 35 weeks pregnant and you have attended the hospital/clinic experiencing symptoms meaning you might be in preterm labour.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

If you decide to take part, the midwife/doctor who is looking after you will ask you sign a consent form, complete a short questionnaire and contact details sheet. Part of the usual care offered to women showing signs of pre-term labour is a vaginal speculum examination.

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During this assessment the midwife/doctor will have checked to see if your cervix is dilating, if there is any vaginal bleeding, or if there has been any rupture of membranes (waters breaking). At this point, if there are none of these symptoms, you may be offered a swab which will be taken to test for fetal fibronectin.

Is the Fetal Fibronectin swab test routine?

Yes. This swab is taken during the speculum examination after the initial assessment is done. This test is offered to women showing signs of preterm labour regardless of whether they are involved in this research or not. This test is not harmful to your baby.

What happens after the swab is taken?

The swab is sent to be analysed, which can take about 10 minutes. Depending on the result of the test, your midwife/doctor will decide what care is best for you and your baby.

1-2 days after having the swab taken, you will be asked to complete a second, short questionnaire and send this back to us in a pre-paid envelope.

When you have had your baby, the midwife will provide details to the research team of you and your baby's health and birth details.

What are the possible benefits of taking part?

Being part of this study will not change how you are managed and you will not experience a direct clinical benefit. However, your participation will add to our knowledge of management of women showing signs of pre-term labour in the future. Some people also enjoy knowing that they have contributed to clinical research.

What are the possible disadvantages/ risks of taking part?

If you decide to take part in this research you will receive the same care as if you do not. The fFN test being done is part of the care offered to any women showing signs of pre-term labour. There are no disadvantages or risk to you or your baby's health, however, filling out the questionnaires may take up some of your time.

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How long is the study running for?

We are planning to recruit women for 12 months at several hospitals around the UK. We hope to get data from at least 1600 women who have the fFN test done.

Who should I speak to if I'm interested in participating?

If you are interested in participating in this study please speak to your midwife/obstetrician. You can also visit our website (www.xxx.xxx.xx.) to obtain further information.

Thank you for taking the time to read this information sheet and considering to take part in the study.

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