What if there is a problem?

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. Please contact: Principle Investigator Jenny Carter (jenny.carter@kcl.ac.uk or 020 7188 3641).

If you have a complaint, you should talk to your research doctor who will do their best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through the Guy's and St Thomas' Patient Advisory Liaison Service (PALS) on 020 7188 7188, address: PALS, KIC, Ground floor, north wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH .

This study is co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation Trust. The sponsors will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation and the Trust having a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of clinical negligence by its employees, brought by or on behalf of a study patient but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of the study?

This study is part of a PhD programme funded by the National Institute of Health Research. The results will be shared with clinical staff, published in health care journals and presented at midwifery and medical conferences. You will not be identified in any report/publication.

Who is paying for this research?

The National Institute for Health Research has funded this study as part of a Clinical Academic Training Fellowship.

The researchers working on this project are paid from this award or through local NHS Trust R&D department funding.

Who has reviewed this study?

The full title of this study is "Threatened preterm labour: a prospective cohort study of a clinical risk assessment tool and a qualitative exploration of women's experiences of risk assessment and management." It has been reviewed and approved by this NHS Trust's Research & Development Department and an NHS Research Ethics Committee (R&D Ref: RJ115/N074; REC Ref: 14/LO/1988).

What do I do if I have further questions or want to take part?

For further information please contact:

Jenny Carter
NIHR Clinical Academic Training
Fellow/Research Midwife
jenny.carter@kcl.ac.uk
tel: 020 7188 3641

or

Annette Briley
Consultant Midwife/
Clinical Trial Manager
tel: 020 7188 3643

Women's Health Academic Centre
10th Floor, North Wing
St Thomas' Hospital
London SE1 7EH

Thank you

for taking time to read this leaflet

Guy's and St Thomas' NHS
NHS Foundation Trust

Threatened preterm labour: risk and care management

Part 1:

A tool for assessing risk

Participant Information Sheet

Can you help?

PIS version 2a: 09/12/2014

Background

Most babies are born at the right time, after 37 weeks of pregnancy. If pregnant women go into labour too soon, there are treatments that can reduce the chance of problems, such as admission to hospital and medicines to slow labour down and help the baby's lungs, if it is born early. It is important, then, that women who think they might be in labour tell their midwife or doctor if they think this is happening.

Many women experience symptoms of "threatened preterm labour" (TPTL) for example, tightenings and/or abdominal pain, but most of these women are not in labour, and the symptoms will settle down on their own. Sometimes it is hard to know whether symptoms are the start of early preterm labour, so many are admitted to hospital and given medicines they may not need.

Some factors, such as whether a woman has had a baby early before, and some test results, like fetal fibronectin and cervical length, are useful when considering how likely it is that labour is starting. Because a number of factors are involved it is quite complicated, so in this study we want to develop a risk assessment tool that will combine these factors and give a risk score (percentage risk of preterm birth) that will help doctors and midwives decide whether treatment is necessary or not.

Why have I been chosen?

You have been asked to take part because you are under 35 weeks' pregnant and have been experiencing symptoms that might mean you are in labour.

What do I have to do if I take part?

You will be assessed in exactly the same way whether or not you participate in this study. You will have a high vaginal swab to assess levels of a natural protein called fetal fibronectin. This is not normally found in high levels in vaginal fluid until just before labour starts. Some women also have the length of their cervix measured by ultrasound scan. These tests do not harm the baby.

If you take part in this study the only difference will be that you agree to information about you and your pregnancy (including results of any tests you have had) being collected and used to see if a risk assessment tool can accurately predict whether or not you give birth early.

After signing a consent form, you will be asked about your medical history and about this and any previous pregnancies. We also want to know how women feel about their experience of threatened preterm labour, any treatments they were offered and decisions they made. If you are happy to consider talking to us about your experience, please indicate this on the consent form and we will contact you to discuss it further. If you would like to go ahead we will arrange a convenient place and time. The interview will take about an hour.

Will my taking part be kept confidential?

If you agree to participate in the study you will be given a study identification number and the information collected about you will be kept on a study database using that number and not your name. It will not be possible to identify you from the information we collect. The database we use is secure and only accessible to people directly involved in the study.

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. In the unlikely event that you lose capacity to consent after initially taking part in the study, the data will still be used unless you indicate you do not agree to this on the consent form.

What are the benefits of taking part?

You may not benefit personally from taking part, but you may help us develop a risk assessment tool that helps women in the future.

What are the disadvantages of taking part?

Taking part in the study will involve taking some of your time in answering our questions, but all the procedures and tests that are done to assess whether you are in preterm labour are carried out as part of your normal care.