CERCLAGE SUTURE TYPE FOR AN INSUFFICIENT CERVIX AND ITS EFFECT ON HEALTH OUTCOMES (C-STICH)

Participant Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully.

Please do talk to others about the study if you want to.

Doctors name:

Doctors telephone number:

Research nurse name:

Research nurse telephone number:

Part 1: Background to C-STICH

Invitation to take part in the C-STICH Study

You have been approached because your doctor has recommended a cervical stitch as part of your pregnancy care. By helping to keep your cervix (neck of the womb) closed for longer these stitches may reduce the risk of premature delivery. If you decide to take part in C-STICH your treatment plan throughout your pregnancy will remain the same.

What is the purpose of the study?

There are two types of threads commonly used for cervical stitches. One thread is made of a single strand; the other is made of strands woven together. Woven threads are sometimes thought to be stronger and easier to remove before birth. However, they might encourage infection, which can trigger an early start to labour.

In contrast, a single strand thread is considered by some to be less likely to cause infection. However, others think this thread can cut the cervix and be harder to remove.

At the moment there is no evidence as to which is the best type of thread to offer to women who are having a stitch to prevent their baby being born too soon. This is why we are doing C-STICH. Your doctor is happy to use either type of thread.

Do I have to take part?

It is entirely up to you if you want to take part in this study. You do not have to take part if you don't want to, and you do not have to give a reason why. If you do not want to take part in this study then the standard of care you will receive will not be affected and you would still be advised to have the cervical stitch.

What will happen to me if I take part?

If you agree to take part in C-STICH you will be asked to sign a consent form.

The type of thread used will be chosen at random and neither you nor your doctor can pick what it will be, and you won't know which type of thread is used for your stitch. You will have an equal chance of the thread being a single strand thread or a woven thread. Studies where people are divided into groups in this way are called 'randomised controlled trials', which are considered the standard and most reliable way of comparing different treatments.

When the trial is finished we'd like to send your baby's NHS number to NHS Digital (England and Wales) or ISD Scotland, a Department of Health sponsored public body, to see how your baby is doing up to one month after it is born. We would also like to collect information from your medical notes, ie., those held with your GP, or yours and your baby's hospital notes from the hospital where you had your cervical stitch fitted as well as any hospital where you delivered your baby, including details of your health and the duration of your pregnancy, and details of your baby's health whilst in hospital. If the baby is born pre-term we will collect information until your expected date of delivery. If your baby is born at full term we will collect information until s/he is 28 days old. You will be asked to agree to this when you sign the consent form.

About the operation to insert the cervical stitch

Your stitch will be inserted by the doctor in the way they always do it. Before the stitch is placed we would like, where possible to take a swab from your vagina to see what (if any) bacteria are there.

About the operation to remove the cervical stitch

The stitch is normally removed around 38 weeks of pregnancy or when labour starts. Your doctor will take out the stitch in the way they always do. Where possible, we would like your permission to keep the actual thread. This is to see if there are any bacteria on it. Not all hospitals will be able to test the thread, if they cannot do this the thread will be disposed of in the usual manner. Your clinician will advise if this is available at your site.

If I take part in the C-STICH study, what else will I be required to do?

If you take part in C-STICH you will not need to do anything yourself or complete any extras tests or questionnaires.

What are the risks and discomforts?

As your doctor has recommended that you need a cervical stitch, if you take part in C-STICH then there are no additional risks.

Are there any benefits for me from taking part in the study?

As you have been advised you need to have a cervical stitch you may not gain any *additional* benefit by taking part in the study. By seeing what bacteria grow on your swab and removed stich will help doctors in treating you if any of these grow any "bad" bacteria. By taking part you will help doctors decide which is the best type of thread to offer to women requiring a cervical stitch in the future.

What if there is a problem?

Any complaints you might have will be taken very seriously. Detailed information on who to contact to raise a concern is given in Part 2 (What if there is a problem?).

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making a decision.

Part 2: Conduct of the study

What will happen if I don't want to carry on with the study?

If you do decide to take part in this study but later change your mind then you are free to withdraw from the study at any time. You don't have to give a reason why you have changed your mind. Once the cervical stitch is in place though, it cannot be removed until you are ready to give birth. We would still like to collect the information on how your baby is doing one month after birth and on the duration of your pregnancy regardless of whether you withdraw from the study and whether you deliver at a different hospital.

In the unlikely event of you losing the ability to give continued consent during the study we would like to keep data that we have already collected about you and include it in our study.

Will information about me be kept confidential?

Yes. Like your medical records all information collected in the study will be held securely and remain strictly confidential. If you agree to take part, your doctor will send basic information about you and your condition to the study's central organisers at the University of Birmingham's Clinical Trials Unit.

No information which can be used to identify you will be published in the study report.

Occasionally, inspections of clinical study data are undertaken to ensure that, for example, all participants have given consent to take part, so a copy of your consent form will be sent to the C-STICH study office at the University of Birmingham Clinical Trials Unit. The Birmingham Women's and Children's NHS Foundation Trust and NHS Trusts are responsible for the good conduct of the C-STICH trial, so responsible individuals from these organisations may be given access to data to check we are complying with regulations. But, apart from this, only a very small number of study organisers will have access to your personal data.

Involvement of the General Practitioner/Family doctor (GP)

With your consent we will inform your GP of your participation in the C-STICH Study. We may need to collect a few important details from your GP, such as information on the birth of your baby.

What will happen to the results of the research study?

The results of this study will be reported in a medical journal and talked about at maternity meetings. It is expected that the first results will be published about two years after the study finishes recruiting women. A summary of the results will be available on the trial website www.birmingham.ac.uk/C-STICH and from the charity SANDS www.uk-sands.org.uk.

Who is funding and organising the research?

C-STICH is being funded by the National Institute for Health Research's Health Technology Assessment programme (NIHR HTA). This is a government funded organisation whose aim is to improve the standard of care in the NHS.

The study is being sponsored by the Birmingham Women's and Children's NHS Foundation Trust, and co-ordinated by University of Birmingham Clinical Trials Unit.

No one involved is being paid for recruiting women into the study. Patients are not paid to take part either, but their help in finding out more about how best to prevent a cause of premature births is very much appreciated.

Who has reviewed the study?

This study has been approved by the Cambridgeshire and Hertfordshire Research Ethics Committee whose role is to ensure your safety, rights, wellbeing and dignity at all times.

This study has also been approved by each hospital taking part in the trial.

What if there is a problem?

You retain the same legal rights as any other patient treated in the National Health Service. If you are harmed by taking part in this research project, there are no special compensation arrangements. If harmed due to someone's negligence, then you have grounds for a legal action but you may have to pay for it. If you are not satisfied with any aspect of the way you have been approached or treated during the course of this study,

you should first speak to the lead study Doctor or Research Nurse/Midwife named on the front cover of this information sheet. If you are still unhappy and wish to complain formally, you can do this through the National Health Service complaints procedure. Details can be obtained from the hospital's PALS (Patient Advice and Liaison Service) Office. The PALS Office offer confidential advice and will advise you how to contact someone for independent advice. You will find the PALS Office at [Enter local PALS location/contact details here]. Participation in this study will not affect any private health insurance.

Do you have any further questions?

If you have any questions about the study feel free to ask your doctor or clinic nurse. Their names and telephone numbers are given on the front of this leaflet.

Thank you for taking the time to read this Participant Information Sheet about the C-STICH Study.