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**Observational Study**

**Patient Information Sheet**



**Emergency Cervical Cerclage to Prevent Miscarriage and Preterm Birth**

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Thank you for taking time to read this information sheet. We understand that this has been a very sensitive and difficult time for you but we would like you to consider taking part in the C-Stich2 Observational study.

Sometimes the neck of the womb (cervix) starts to open early and the bag of waters (amniotic sac containing amniotic fluid) around the baby comes through the neck of womb. When this happens too early in a pregnancy (before 28 weeks), there are a limited number of treatment options. Doctors do not know which treatment is best for mother and baby. These treatments include expectant management combined sometimes with antibiotics, progesterone, medicines to stop the womb contracting or emergency cervical cerclage. The C-STICH2 team are running a randomised trial and AN observational study to determine if an emergency cervical cerclage reduces the chance of miscarriage and early birth.

You are being approached about this study because this has happened to you and your midwife or doctor believes you are therefore eligible to take part in the C-STICH2 observational study. The observational study involves you deciding with your medical team all of your medical care (including treatments) and you consenting to sharing this information to help improve the care of women with this condition in the future.

For all women and babies in the observational study, regardless of which treatment you receive, the study will collect details from your medical records of what happens to you and your baby, reporting this information anonymously. The information that you provide will help the research team find out if an emergency cervical cerclage prevents women with this condition from having an early birth. This research and your data will help us to find better treatments for women with this condition. Your information is very important in helping us understand how to look after pregnant women in your situation.

**What would taking part involve?**

Taking part in the observational study would involve no extra visits or differences from the standard care you would normally receive. The study will collect details from the medical records of what happens to you and your baby, reporting this information anonymously. 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 2 years of age. We would also like to collect information from your medical notes, i.e., those held with your GP, or yours and your baby’s hospital notes from the 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. You will be asked to agree to this when you sign the consent form.

All surviving babies will be reviewed at two years of age to assess how they are developing, this will be performed via a questionnaire posted to you to complete.

This questionnaire has been used in many studies and will help the research team work out if all babies are developing in the same way. A member of the trial team may need to contact you for further trial follow-up should there be any data missing.

**Will my taking part in this study be kept confidential?**

If you agree to take part in this study, your details and any information collected about you for this research will be handled, stored and destroyed in accordance with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018.

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 healthcare team 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.

Who is organising and funding the research?

C-STICH2 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 the University of Birmingham Clinical Trials Unit (BCTU).

No one involved is being paid for recruiting women into the study. Women 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.

 **How have patients and the public been involved in this study?**

A group consisting of women who have experienced the condition and treatments and members of the public helped to develop this research topic and the research questions that should be asked. Members of this group are also co-applicants and will continue to be involved in the study.

Potential participants were involved in reviewing the Participant Information Sheet and in describing the inclusion and exclusion criteria for people taking part in this study. In designing this study we have taken into account women’s opinions on the frequency of participant visits and the tests that we will carry out.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given a favourable opinion by the East Midlands—Leicester South Research Ethics Committee.

What will happen to any data I give?

The Birmingham Women’s and Children’s Hospital NHS Foundation Trust (BWCH) is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

The University of Birmingham will keep identifiable information about you until the main results of the study have been published. After this time, identifiable information will be safely destroyed. Anonymised data will be stored securely at the BCTU for at least 25 years after the end of the study. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

The University of Birmingham will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Birmingham and regulatory organisations may look at your research records to check the accuracy of the research study. The NHS organisations who may approach you about taking part in the study, with your permission, will pass your contact details to the University of Birmingham. The only people in the University of Birmingham who will have access to information that identifies you will be people who need to contact you, for example, to invite you to participate in the study or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number (CHI number in Scotland) or contact details.

Involvement of General Practitioner

With your permission we will inform your GP of your participation in the C-STICH2 study. We may need to collect from your GP the location of the birth of your baby should you deliver at a different hospital from your current hospital.

**What if something goes wrong?**

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions.

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 or Patient Advice and Support Service in Scotland. They offer confidential advice and will advise you how to contact someone for independent advice. You will find your local Office contact details at the end of this leaflet.

Alternatively, you can contact the research sponsor at bwc.research@nhs.net.

What if I do not want to take part?

If you do not want to take part in the study, this will not affect the care you receive.

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. You will be able to withdraw from the study within two weeks after the final data collection without giving a reason. If you withdraw from the study, we will keep the information about you that we have already collected.

Sources of further support

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| **Tommy’s**Image result for tommys logo www.tommys.org   | midwife@tommys.org.uk0800 014 7800Monday-Friday, 9-5 |
| **Miscarriage Association**Image result for miscarriage association www.miscarriageassociation.org.uk   | info@miscarriageassociation.org.uk01924 200799Mon-Fri, 9am-4pm  |
| **Sands** Stillbirth & Neonatal Death Charitywww.sands.org.ukImage result for sands logo   | helpline@sands.org.uk08081643332 |
| **Bliss**www.bliss.org.uk   | hello@bliss.org.uk 0808 801 0322  |
| **The Pinks N Blues** Pregnancy Loss Support Group   | enquiry@thepinksnblues.co.uk@thepinksnblues |
|  **Incompetent Cervix UK**  Facebook group for anyone and everyone in the UK and Ireland who would like advice, info or support on any aspect of cervical insufficiency. |

Contact Information

If you would like to speak to someone about the study please contact the trials team at:

**c-stich2@trials.bham.ac.uk**

**0121 414 3902**

**www.birmingham.ac.uk/c-stich2**

Support can also be found through the NHS Patient Advisory and

Liaison Service (PALS) or equivalent

(Patient Advice and Support Service in Scotland)

ATTACH LOCAL PALS and RESEARCH TEAM
INFO STICKER HERE

