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Emergency Cervical Cerclage to Prevent Miscarriage and Preterm Birth: a Randomised Controlled Trial

PATIENT INFORMATION SHEET

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Thank you for taking the time to read this information sheet. We understand that this will be a very difficult time for you and that you will be feeling very scared for yourself and your baby. Our understanding of why this happened to you is sadly very limited and therefore we do not know which is the safest treatment to give the best outcome for you and your baby. This leaflet will explain what is happening, about the treatments available and a research study that you can decide to enter to try and help us find out which is the best way to help women who are in this situation. Your healthcare team will also talk to you about the treatment options available.

We know that parents in this situation often need extra support and so at the end of this leaflet we have put the contact details for organisations that can help you.

Brief summary

We would like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it will involve for you. A member of our research team will go through this information sheet with you, to help you to decide whether or not you would like to take part in the study and to answer any questions you may have. Please feel free to talk to your partner and others about the study if you wish.

This Patient Information Sheet tells you the purpose of the study, what will happen to you if you take part and detailed information about the conduct of the study. Please do take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

Purpose and background to the research

Sometimes the neck of the womb can start to open early and the bag of waters (amniotic sac containing amniotic fluid) around the baby can come through the neck of womb (please see Figure 1).

If this happens too early in a pregnancy (before 28 weeks), there are a limited number of treatment options. Healthcare team s do not know which one is best for mother and baby. These include expectant management combined sometimes with antibiotics, progesterone, medicines to stop the womb contracting or emergency cervical cerclage.

An emergency cervical cerclage is the placement of a stitch around the neck of the womb after replacement of the bag of waters. This can potentially prolong the pregnancy so that the baby can be born when they are bigger and stronger. This may give babies a better chance of surviving and suffering from less complications of prematurity.

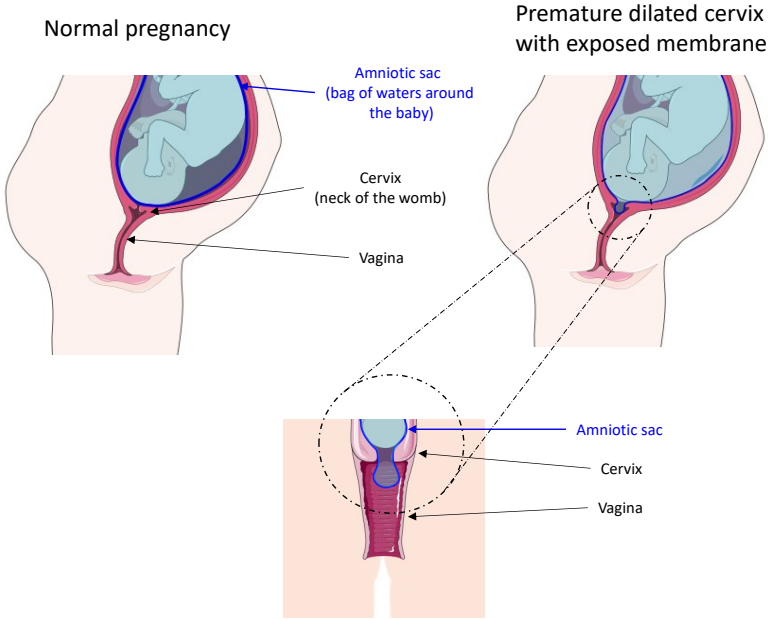

Figure 1 - Anatomy of exposed membranes

Healthcare team s do not know if an emergency stitch works - there is some evidence it may prolong pregnancy, preventing the complications of being born too early, but it is possible that it may also speed up delivery by causing infection or cause damage to the neck of the womb of the mother causing problems in future pregnancies.

It is therefore very important to perform a study to decide if emergency stitches are a suitable treatment option for women and their babies when the neck of the womb is open and the bag of waters (amniotic sac) is bulging into the vagina.

Why have I been chosen?

You have been approached to consider the study because the neck of your womb has begun to open and the bag of waters around your baby has come through.

What would taking part involve?

The best way to work out which treatment is best and safe for you and your baby is to ask women to have their treatment decided at random. This is what we need to do to ensure we know what is best for the women and babies to prevent harm in the long term. Your Healthcare team will provide us with information to ensure that you are able to take part and that you want to take part. The management that you receive will then be randomly decided based on a computer algorithm. This means that you have a 50% chance of being given expectant management and a 50% chance of being given an emergency stitch.

If you take part, you will be monitored or have an emergency cervical stitch.

If you are allocated to expectant management, your healthcare team will discuss your individual plan with you. You can have other possible treatments such as antibiotics, progesterone and womb relaxants. These potential treatments, along with waiting to see what happens, may mean that your pregnancy progresses to a time where your baby is born and can survive.

If you are allocated to receive an emergency cervical stitch, your healthcare team will talk to you about the operation in more detail

and explain the risks and benefits and ask you to sign a consent form for the procedure. You will then have the procedure at your hospital with the healthcare team s currently caring for you. This procedure is performed under a regional anaesthetic (like an epidural) with you awake in theatre. The procedure takes around 60 minutes.

The risks your healthcare team will talk about include the risk of infection - this includes the risk of infection for you and a risk of infection developing around your baby and in your baby when they are born. There is a risk of not being able to perform the operation because the neck of the womb is too open, or the bag of waters cannot be replaced inside the womb. During the procedure, the bag of waters (amniotic sac) around the baby might be broken and this can cause a miscarriage, or problems with your babies' lung development due to the lack of amniotic fluid around the baby.

For all women and babies in the study, regardless of which treatment they 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 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. 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. A member of the trial team may need to contact you for further trial follow-up should there be any data missing.

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.

What are the possible benefits of taking part?

We do not know whether you will benefit personally from taking part in this study, but the knowledge gained thanks to your help, will inform future studies and treatment, potentially leading to improved treatment of women with this condition in the future.

What are the possible disadvantages and risks of taking part?

We do not know which treatment is best and so the main risk in taking part in the study is that you have a treatment that did not help prevent a miscarriage or preterm birth. We will not know this until the end of the study, when we have looked at all of the results.

The potential risks and benefits of the treatments available will be discussed with you by your Healthcare team as part of your care.

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.
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.

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

A group consisting of patients 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 trial we have taken into account patient 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.

Will my taking part in this study be kept confidential?

Yes. If you agree to take part in this trial, 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. Occasionally, check 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-STICH2 trials office at the University of Birmingham Clinical Trials Unit. Relevant sections of your medical notes and data collected during the study may be looked at by appropriate individuals from the University of Birmingham Clinical Trials Unit research team, representatives of the sponsor, from regulatory authorities, or from the NHS Trust. The Birmingham Women's and Children's NHS Foundation Trust and NHS Trusts are responsible for the good conduct of the C-STICH2 trial, so

responsible individuals from these organisations may be given access to data to check we are complying with regulations.

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. You can find out more about how we use your information by contacting us (details on back page).

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 trial. 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. Once the cervical stitch is in place though, it cannot be removed until you are ready to give birth.
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.

Observational Study

If you have decided not to take part in the randomised study but you would still like to contribute to this research, your midwife or healthcare team will discuss taking part in the observational study. The observational study involves you deciding with your medical team whether you have an emergency cervical cerclage or not. All of the same information will be collected as described in the randomised study including information about what happens to you and your baby, in addition to the information collected from your medical notes. If appropriate as in the randomised study you will also be sent a questionnaire when your baby is two years old, so that we can follow your baby's development. The information that you provide will help the research team work out if an emergency cervical cerclage prevents women from having an early birth. This research and your data will help us to find a more robust approach in treating women with this condition. Your information is very important and useful to us.

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.

Do you have any further questions?

Thank you for taking the time to read this information. If you have any questions then please feel free to get in touch with us using the contact details on the back of this leaflet. For more information you can also visit our website at **www.birmingham.ac.uk/C-STICH2**

Also, the UK Clinical Trials Gateway (**www.ukctg.nihr.ac.uk**) is a useful resource, providing information about the process of and reasons for taking part in medical research, which may be of interest to you.

Sources of further support

Tommy's
www.tommys.org
midwife@tommys.org.uk
0800 014 7800
Monday-Friday, 9-5

Miscarriage Association
www.miscarriageassociation.org.uk
info@miscarriageassociation.org.uk
01924 200799
Mon-Fri, 9am-4pm

Sands
Stillbirth & Neonatal Death Charity
www.sands.org.uk
helpline@sands.org.uk
08081643332

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

I AM RESEARCH
Be part of the solution