The Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH)

CRF1: C-STICH Randomisation Notepad

Please complete this form before attempting to randomise your patient.

Randomising Centre Name: .....

Randomising (Consenting) Clinician Name: .....

Participant Details:

Participant Initials: ☐☐☐

Date of Birth: D D - M M M - Y Y Y Y

Hospital Number: ☐☐☐☐☐☐☐☐☐☐

NHS Number: ☐☐☐☐☐☐☐☐☐☐

CHI Number ☐☐☐☐☐☐☐☐☐☐ **(Scotland)** :

Participant Ethnicity:

Asian		Black (Other)		White (British)	
Asian (Indian)		Chinese		White (Irish)	
Asian (Pakistani)		Mixed (White / Black Caribbean)		White (other)	
Asian (Other)		Mixed (White /		Any other	
Black (African origin)		Mixed (White / Asian)		Not Given	
Black (Caribbean origin)		Mixed (Other)			

Pregnancy Details:

Weeks Days

Gestational age at randomisation: ☐☐ ☐☐

Expected date of delivery: D D - M M M - Y Y Y Y

What is the Gravida?

Number of 1st trimester losses ☐

Number of mid trimester losses ☐

Number of termination of pregnancies ☐

What is the Parity?

Number of live births < 33^{+6} weeks ☐

Number of live births 34 to 36^{+6} weeks ☐

Number of live births > 37 weeks ☐

Ultrasound findings:

(Please complete if the participant had cervical length ultrasound scanning)

	YES	NO
Has the participant had an cervical length ultrasound scan?	☐	☐

If yes please answer the following two questions.

What was the shortest cervical length before cerclage insertion? (mm) ☐

	YES	NO	DON'T KNOW
Was there evidence of cervical funnelling?	☐	☐	☐

ELIGIBILITY CRITERIA:

If any of the grey shaded boxes are ticked the participant is not eligible to participate in C-STICH

Patient Inclusion Checklist: All 'Yes' boxes must be ticked for the woman to be eligible	**YES**	**NO**
Is this woman carrying only one baby?	☐	☐
Do you deem this woman to be at risk of pre-term birth?	☐	☐
Are you happy for this woman to undergo a vaginal cervical cerclage?	☐	☐
Are you happy to place the cervical cerclage with either a monofilament or braided suture material?	☐	☐
Is this woman aged 18 years or more?	☐	☐
Is this woman able and willing to give informed consent?	☐	☐

Patient Exclusion Checklist: All 'No' boxes must be ticked for the woman to be eligible	**YES**	**NO**
Has this woman taken part in C-STICH previously?	☐	☐
Does this woman require a rescue cerclage?	☐	☐
Will the cerclage be placed by any route other than vaginally?	☐	☐
Does the women have ruptured membranes?	☐	☐

CONSENT DETAILS:

Date Consent form signed: D D - M M M - Y Y Y Y

Please write the Version number of the consent form used here……

Randomisation minimisation:

What is the PRIMARY indication for cerclage (Please tick one box only)?:

- A history of three or more previous midterm losses or premature births (≤ 28 weeks). ☐
- Insertion of cervical sutures in previous pregnancies. ☐
- A history of mid trimester loss or premature birth with a shortened (≤ 25 mm) cervix. ☐
- Women whom clinicians deem to be at risk of preterm birth either by history or the results of an ultrasound scan. ☐

	YES	NO
Do you plan to dissect the bladder? *If you won't know the answer to this question until you get to theatre you should tick 'NO'.*	☐	☐
Progesterone treatment (either current or intention to commence)?	☐	☐

Supporting Clinical Information (at clinicians discretion):

Other Trial Participation:

	YES	NO
During this pregnancy has this woman, or will this woman be simultaneously taking part in an IMP trial or other trial for the prevention of pre-term birth?	☐	☐

If 'YES', please state which trial this is: ……..

Randomisation Procedures:

To randomise your patient between a monofilament and braided suture please call **0800 953 0274** between 0900 – 1700 hrs Monday to Friday.

Out of hours you may call **07796956076** or **07919920735** or enter the patient online at: https://www.trials.bham.ac.uk/CSTICH (24 hours a day).

Randomisation Allocation:

Please tick the box next to the suture material patient has been randomised to:

Monofilament ☐

Braided ☐

Please write the patient's four digit trial number here: ☐☐☐☐

Please now write the trial number at the top of each preceding page.

Some information about you:

Print Name: ……

Signature: ……

Today's date: D D - M M M - Y Y Y Y

THANK YOU FOR RANDOMISING YOUR PATIENT TO THE C-STICH TRIAL

Please send a copy of this form along with a copy of the consent form to:

The C-STICH Trial, FREEPOST RTGS-UKLK-JKHS, Birmingham Clinical Trials Unit, Institute of Applied Health Research, University of Birmingham, B15 2TT or by fax to

0121 415 9136

If emailing this Randomisation Notepad or Consent form: The Randomisation Notepad and Consent form contain participant identifiers, and so cannot be sent via normal email. Instead please email them using a secure/encrypted method. If you are at all unsure, the Trials Office can provide guidance on how to do this—contact cstich@trials.bham.ac.uk