C-Stich

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Objectives

- Overview of study
- The Principal Investigator
- Key aspects of role (PI)
- Managing challenges
- The Research Midwife
- Key aspects of the role (RM)
- **Women's stories**
- Awards and successes

C-stich

- Preterm birth is a major challenge in obstetrics
- Of 50,000 babies born prematurely every year, 1,500 will die (ONS,2016)
- Huge economic implications in NHS
- Devastating for families

Overview of C-Stich

- **Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH)**
- Obstetric and gynaecology departments in hospitals within the UK.
- A multi-centre, open, randomised controlled trial of 2050 women presenting at obstetric units and deemed to be at risk of an insufficient cervix, and scheduled to be treated by cervical cerclage.
- Open until June 2020

Aims of C-Stich

- To examine the effect of using a monofilament suture material compared with a braided suture material on pregnancy loss rate (defined as miscarriage, stillbirth, neonatal death in the first week of life) and neonatal mortality up to one month post-delivery in women deemed to be at risk of an insufficient cervix and treated with cervical cerclage.

- To assess the effect of suture material on other pregnancy and neonatal outcomes, exploring the variation in effect between McDonald's and Shirodkar's cerclage, the variation in effect between the indication for cerclage and to produce advice and a video clip to illustrate best practice in cerclage stitch insertion and removal

Inclusion and exclusion criteria

- Women over 18 years old with a singleton pregnancy and presenting with indications for cervical cerclage are included.

- Emergency cerclage and women previously included in the C-Stich trial are excluded.

The Principal Investigator

- An individual responsible for the conduct of the research at a site

The PI role

- The dignity, rights, safety and wellbeing of participants are given priority at all times.
- The study has Health Board R&D approval prior to commencement.
- The study has the appropriate Research Ethics Committee (REC) approval
- The study follows the approved protocol and any protocol amendments

The PI role (continued)

- Procedures are in place to ensure the collection, processing and storage of high quality accurate data in accordance with the Data Protection Act 1998 and the Caldicott Principles.
- Each member of the research team is suitably qualified by education, training and experience to conduct the study, and their qualifications and training details are documented.
- The study is conducted by the members of the research team through authorised delegated responsibility.

The PI role (continued)

- Students, new researchers and those with delegated responsibility involved in the study have adequate supervision, support and training.
- Reports on the progress and outcomes of the work required by the R&D Department, the funder, research sponsor, REC and regulatory bodies are produced on time and to an acceptable standard.
- Internal and external monitors/auditors are given access to documents, devices and equipment as necessary.

The PI role (continued)

- Arrangements are in place to archive the data when the research has finished, and to make it accessible. Records must normally be kept for 15 years.
- Leadership, supporting staff, managing challenges, coordinating the research team

Managing challenges

- Investigate the problem
- Support research staff with concerns
- Education, training and raising awareness
- Considering options
- Documenting actions
- Celebrating success

Role of the Research Midwife

- Research midwives play a key role as patient advocate, ensuring patient safety and protection and that patients are well supported in a research study

Key aspects of the role

- Contact the potential recruit and confirm she has received the Patient information sheet
- Arrange to meet with the potential recruit
- Explain the study fully, that it is optional and will not effect care if she chooses not to participate
- Reassure confidentiality and anonymity of data

Research midwife role (cont)

- Provide contact numbers
- Gain informed consent
- Randomise patient
- Inform all appropriate members of the team of outcome of randomisation (e.g.Inform gynae theatre of type of suture material)
- Maintain a high standard of documentation, inform relevant health professionals as protocol (e.g. GP)

Research Midwife role (continued)

- Complete CRFs and copy and document appropriately
- Maintain ongoing data collection
- Report any variations to the PI and the study centre
- Staff training and raising awareness of the study
- Ongoing communication with study centre

Women’s stories

- **Recruit A**

  ‘A’ was identified to the research team after being referred to an obstetric consultant at 13 weeks of pregnancy, due to her complicated and sad obstetric history. After a full discussion with the consultant, a transvaginal scan showing a shortened cervix, and a clinical plan for cervical cerclage, ‘A’ was given a C-stich PIS to read and gave her permission to be contacted by the research midwife.

Recruit A

- A home visit for potential recruitment was arranged. ‘A’ explained to the RM that she had lost two babies previously- one at 23 weeks gestation and one at 22+4. Neither her son nor daughter had survived. This had obviously been a very distressing time for the whole family. She was happy to participate in the study and very keen to have cerclage for the first time.

Recruit A

- Informed consent was given. Cerclage placement took place at 15 weeks gestation, recruit ‘A’ stayed in hospital overnight and had prophylactic antibiotics, there were no complications. The research midwife accompanied her during the procedure. The procedure was successful and the pregnancy progressed to 37 weeks gestation. Between 22 and 26 weeks, recruit ‘A’ made contact with the research team and her community midwife for additional emotional support.

Recruit A

- At 37 weeks ‘A’ went to hospital to have the cervical suture removed. She subsequently went into labour and had a vaginal birth of a healthy little boy. Despite good apgars at birth, he did go to the neonatal unit for 72 hours for feeding support but both mother and baby were discharged from hospital after three days and both were healthy in the post natal period.

Recruit A

‘I was very happy to be involved in a study that could potentially help myself or others in the future and prevent the heartache that my family has been through. It was reassuring to know that the doctors and midwives want to keep making care the best it can be. We are delighted with our son and want to thank everyone for the wonderful care. It was lovely having the extra support’

Recruit B

‘B’ is a lady who has a healthy four year old son (with a non eventful pregnancy and a vaginal birth). She had a miscarriage in early 2017 and at this time was found to have cancer of the cervix. She subsequently had some LLETZ procedures and invasive cervical surgery. Sadly she will need a hysterectomy and was given various options but decided she wanted to complete her family first.

Recruit B

Due to surgery, her cervix was recognised as shortened and unable to support a pregnancy to full term. Cerclage was offered and accepted and ‘B’ was very happy to join the C-stich study.

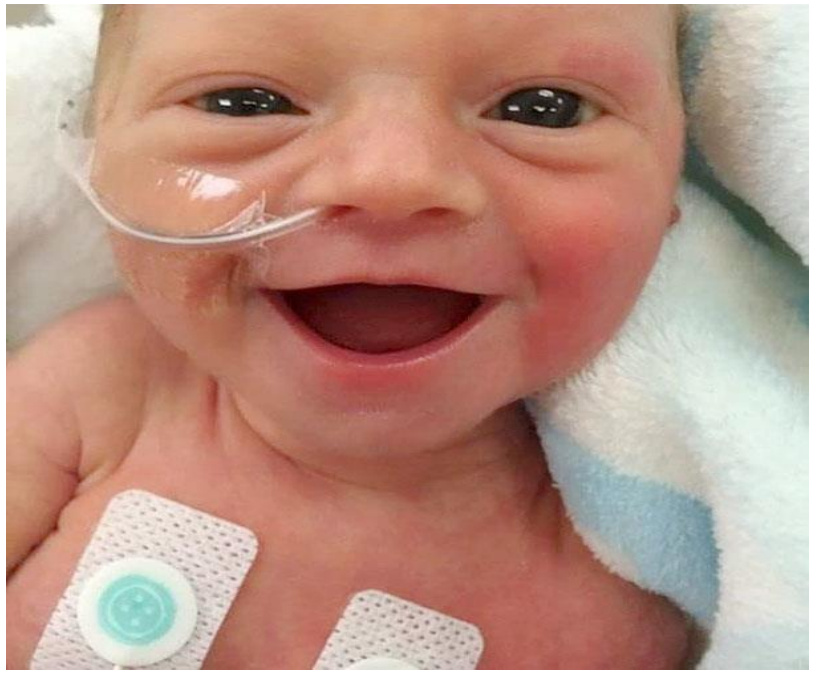
A caesarean section and removal of the cervical suture is planned for June 2018, and following this ‘B’ will have a hysterectomy and further treatment.

The pregnancy is progressing well.

Recruit B

‘I was happy to participate in the study. Our lives have been turned upside down in the past year but we have been so grateful that we have had access to such great care. If we lived in a developing country the outcomes would have been very different and we are thankful that not only are we supported by a great NHS, but also that we can see everyone is trying to keep making it better. Thank you’

Quotes from women about C-stich at ABUHB



‘I was happy to help’
‘It was like having an extra midwife in the beginning’
‘They explained everything really well ‘
‘I would’ve liked to see them more’
‘Anything that helps in the future is worth it’

Awards and successes

- Award for ‘Most Improved Recruiting Site’
- Award for ‘Top recruiter for Medium Sized site’
- Award for ‘Top Recruiting site in Wales’
- Reassuring site assessment
- Selected as a site for C-Stich 2
- Huge commendations across social media as being an excellent research site

Why we do research at ABUHB

- To raise the research profile across the HB and nationally
- Continued professional development of staff
- To strive to constantly improve care and services to women and their families
- To honour our responsibilities to the NMC
- To engage with the Maternity Services for Wales strategic vision

Questions?