ISRCTN15068651 https://doi.org/10.1186/ISRCTN15068651

An investigation into the role of previous in-labour caesarean section in future preterm birth risk and potential management strategies

Submission date
23/09/2019

Recruitment status
No longer recruiting

Registration date
25/09/2019

Overall study status
Completed

Last Edited
17/10/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 14/12/2021:
Background and study aims:
There are multiple factors that predispose women to preterm birth such as surgery to the neck of the womb, previous preterm birth and multiple pregnancies. A new factor now found to be contributing to this risk is if the mother has had a previous full dilatation caesarean section (FDCS) in labour particularly when she is 10 cm dilated. It is not known how significant this risk is in the UK and the mechanism is not proven but what is known is that it particularly affects pregnancies under 28 weeks and also results in many late miscarriages (14-23+6 weeks). New NHS Commissioning guidelines and Saving Babies Lives Care Bundle have now recommended screening all women with a previous FDCS because of this new widely reported risk. It is not known whether a cerclage (stitch) inserted into the cervix, first-line prophylactic treatment in many UK units for a short cervix or alternatively progesterone or arabin pessary, works in this group of women. Researchers have never imaged the cervix looking for injury in this FDCS group of women and compared it to assessment with routine transvaginal ultrasound. It is also not known if a cut off of 25 mm is a short cervix in women with a previous FDCS. Furthermore, it is not known how many women with a previous caesarean at 4-9 cm dilatation have a risk of preterm birth in the future nor if the current tests of cervical length and fibronectin test work well to predict preterm birth in these women.

Who can participate?
CRAFT-OBS (observational study): women with a previous caesarean in labour when they are dilated 4 cm up to 10 cm
CRAFT-IMG (imaging substudy): women booked at University College London Hospital or St Thomas' Hospital with a previous full dilatation caesarean

What does the study involve?
CRAFT-OBS: researchers look at the participants' current pregnancy records and find out when they deliver as well as details about their previous caesarean in labour.
CRAFT control group: a non-identifiable minimal dataset of the entire population of women delivering at study sites with only a history of previous term vaginal delivery.

CRAFT-IMG: transvaginal ultrasound and magnetic resonance imaging (MRI) are used to assess any scars in the cervix to try to work why previous full dilatation caesareans pose a future preterm birth risk

What are the possible benefits and risks of participating?
There is no direct benefit to participating in CRAFT-OBS. The time needed to participate in the imaging substudy may be a burden - MRI and transvaginal ultrasound imaging procedures will take about 2 hours in total. There is a safety risk with metallic MRI incompatible devices or objects near the MRI scanner. Heat generation secondary to the MRI scanner during image acquisition is another risk. The risk of noise from the MRI scanner will be minimised by earphones and earplugs. The risk of incidental findings also remains - however, if an overt defect in the cervix is noted this may affect the obstetrician's choice of placement of a cervical cerclage or the type of cerclage (vaginal or abdominal) in a future pregnancy.

Where is the study run from?
King's College London and Guy's and St Thomas Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2019 to April 2024 (updated 18/05/2021, previously: April 2022)

Who is funding the study?
J.P. Moulton Charitable Foundation

Who is the main contact?
Dr Agnieszka Glazewska-Hallin
agnieszka.glazewska-hallin@kcl.ac.uk

Previous plain English summary:
Background and study aims
There are multiple factors which predispose women to preterm birth such as surgery to the neck of the womb, previous preterm birth and multiple pregnancies. A new factor now found to be contributing to this risk is if the mother has had a previous full dilatation caesarean section (FDCS) in labour particularly when she is 10 cm dilated. It is not known how significant this risk is in the UK and the mechanism is not proven but what is known is that it particularly affects pregnancies under 28 weeks and also results in many late miscarriages (14-23+6 weeks). New NHS Commissioning guidelines and Saving Babies Lives Care Bundle have now recommended screening all women with a previous FDCS because of this new widely reported risk. It is not known whether a cerclage (stitch) inserted into the cervix, first-line prophylactic treatment in many UK units for a short cervix, works in this group of women. Researchers have never imaged the cervix looking for injury in this FDCS group of women and compared it to assessment with routine transvaginal ultrasound. It is also not known if a cut off of 25 mm is a short cervix in women with a previous FDCS. Furthermore, it is not known how many women with a previous caesarean at 4-9 cm dilatation has a risk of preterm birth in the future nor if the current tests of cervical length and fibronectin test work well to predict preterm birth in these women.

Who can participate?
CRAFT-OBS (observational study): women with a previous caesarean in labour when they are dilated 4 cm up to 10 cm
CRAFT-RCT (randomised controlled trial of treatment): women with a previous full dilatation caesarean and short cervix
CRAFT-IMG (imaging substudy): women booked at University College London Hospital or St Thomas' Hospital with a previous full dilatation caesarean

What does the study involve?
CRAFT-OBS: researchers look at the participants' current pregnancy records and find out when they deliver as well as details about their previous caesarean in labour.
CRAFT-RCT: participants are randomly allocated to be treated with or without a cerclage
CRAFT-IMG: transvaginal ultrasound and magnetic resonance imaging (MRI) are used to assess any scars in the cervix to try to work why previous full dilatation caesareans pose a future preterm birth risk

What are the possible benefits and risks of participating?
There is no direct benefit to participating in CRAFT-OBS. However, all CRAFT-RCT participants will receive close, regular monitoring of their pregnancy, allowing treatments to be administered to improve the baby's outcome if necessary (corticosteroids, magnesium sulfate) in the event of imminent delivery as well as admission depending on clinician opinion. Participants may be at risk of feeling burdened by the time needed to consider participation and consent to the study overall. Those having an optional fetal fibronectin test as part of CRAFT-RCT may experience discomfort during the speculum examination. The minimal risks as a result of inserting a transvaginal cerclage have been identified as bleeding, infection and urinary retention. The time needed to participate in the imaging substudy may be a burden - MRI and transvaginal ultrasound imaging procedures will take about 1.5 hours in total. There is a safety risk with metallic MRI incompatible devices or objects near the MRI scanner. Heat generation secondary to the MRI scanner during image acquisition is another risk. The risk of noise from the MRI scanner will be minimised by earphones and earplugs. The risk of incidental findings also remains - however, if an overt defect in the cervix is noted this may affect the obstetrician's choice of placement of a cervical cerclage or the type of cerclage (vaginal or abdominal) in a future pregnancy.

Where is the study run from?
King's College London and Guy's and St Thomas Hospital (UK)

When is the study starting and how long is it expected to run for?
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Who is funding the study?
J.P. Moulton Charitable Foundation

Who is the main contact?
Dr Agnieszka Glazewska-Hallin
agnieszka.glazewska-hallin@kcl.ac.uk

Study website
https://www.kcl.ac.uk/research/craft

Contact information

Type(s)
Scientific

Contact name
Dr Agnieszka Glazewska-Hallin

Contact details
Dept of Women's and Children's Health
10th floor North Wing
St Thomas' Hospital
Westminster Bridge Rd
London
United Kingdom
SE1 7EH
+44 (0)20 7188 8151
agnieszka.glazewska-hallin@kcl.ac.uk

Type(s)
Scientific

Contact name
Prof Andrew Shennan

Contact details
Dept of Women's and Children's Health
10th floor North Wing
St Thomas' Hospital
Westminster Bridge Rd
London
United Kingdom
SE1 7EH
+44 (0)20 7188 3634
andrew.shennan@kcl.ac.uk

Type(s)
Scientific

Contact name
Dr Lisa Story

Contact details
Dept of Women's and Children's Health
10th floor North Wing
St Thomas' Hospital
Westminster Bridge Rd
London
United Kingdom
SE1 7EH
+44 (0)20 7188 9145
lisa.story@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
261294

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42833, IRAS 261294

Study information

Scientific Title
CRAFT: Cerclarge after full dilatation caesarean section; an investigation into the role of previous in labour caesarean section in future preterm birth risk and potential management strategies

Acronym
CRAFT

Study objectives
Current principal research question/objective as of 14/12/2021:
CRAFT-OBS:
To understand the association between the degree of cervical dilatation during caesarean in labour with risk of late miscarriage or preterm birth in subsequent pregnancies.

CRAFT-IMG:
To identify a mechanism for the increased risk of preterm birth with MRI (magnetic resonance imaging) and transvaginal ultrasound in order to predict those at most risk and whether cervical cerclage would be of benefit

Secondary research questions/objectives:
CRAFT-OBS:
1. Determine the incidence of late miscarriage and preterm birth in women with previous caesarean in labour depending on their cervical dilatation
2. If ultrasound measured cervical length and quantitative fibronectin are carried out as part of clinical care, this data will be collated and help evaluate the ability of these tests to predict risk of preterm birth in women with a history of a caesarean in labour
Control group: population data from study sites to generate preterm birth analysis of women with only previous term vaginal births as control group

CRAFT-IMG:
1. Ascertain whether MRI or ultrasound (or a combination of the two) can accurately predict preterm birth when abnormalities are detected in the cervix
2. Identify which women are most likely to benefit from a cervical cerclage

Previous principal research question/objective:

CRAFT-OBS:
To understand the association between the degree of cervical dilatation during caesarean in labour with risk of late miscarriage or preterm birth in subsequent pregnancies.

CRAFT-RCT:
To assess the efficacy of cervical cerclage for a short cervix ≤25 mm detected by transvaginal ultrasound in a randomised controlled trial of women with a previous full dilatation caesarean section.

CRAFT-IMG:
To identify a mechanism for the increased risk of preterm birth with MRI (magnetic resonance imaging) and transvaginal ultrasound in order to predict those at most risk and whether cervical cerclage would be of benefit.

Secondary research questions/objectives:

CRAFT-OBS:
1. Determine the incidence of late miscarriage and preterm birth in women with previous caesarean in labour depending on their cervical dilatation.
2. If ultrasound measured cervical length and quantitative fibronectin are carried out as part of clinical care, this data will be collated and help evaluate the ability of these tests to predict risk of preterm birth in women with a history of a caesarean in labour.

CRAFT-RCT:
1. Determine if ultrasound-indicated cervical cerclage is effective in women with a history of full dilatation caesarean section and cervical shortening (≤25 mm) in preventing late miscarriage or preterm birth <34 weeks' gestation.
2. Evaluate the impact of cervical cerclage and or standard management on short-term fetal and neonatal outcomes, assessed as a composite of fetal and perinatal death and major morbidity.
3. Assess the impact of both management strategies (i.e. cerclage and standard management) on health economic outcomes for mother and infant in terms of number of nights in hospital; cost data to hospital discharge/28 days post delivery.

CRAFT-IMG:
1. Ascertain whether MRI or ultrasound (or a combination of the two) can accurately predict preterm birth when abnormalities are detected in the cervix.
2. Identify which women are most likely to benefit from a cervical cerclage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/09/2019, London Queen Square research ethics committee (HRA NRES Centre Bristol, 3rd floor, block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 104 8057; Email: NRESCommittee.London-QueenSquare@nhs.net), ref: 19/LO/1270

Study design
Observational; Design type: Treatment, Screening, Prevention, Process of Care, Imaging, Management of Care, Surgery, Active Monitoring, Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Preterm birth risk following in labour Caesarean section when compared to women with term vaginal births

Interventions
Current interventions as of 14/12/2021:
CRAFT-OBS:
This is a multicentre prospective cohort observational study of 4400 pregnant women with a previous history of CS in labour who will be recruited following their booking visit. Women who have had a previous FDCS will be invited to participate in CRAFT-IMG.

Women will be approached by a doctor, sonographer or midwife at or following their booking appointment if they have a history of a previous in-labour emergency caesarean section. They will have until their next routine appointment to read the patient information leaflet, and if interested in taking part, consented by a member of the research team. If their hospital does clinically indicated asymptomatic testing with fibronectin or cervical length, the results of this data will also be collected for the study. We will collect data about any preterm interventions they have had including progesterone, cerclage and arabin pessary options.

CRAFT-RCT: now discontinued
CRAFT control group: population data from study sites during CRAFT recruitment period - women pregnant and delivering with history of previous term vaginal births (control group).

CRAFT-IMG:
This is a prospective sub-study collecting image data and outcomes in a sub-group of women participating in CRAFT-OBS (n=60) Patients will undergo up to 3 extra transvaginal ultrasounds with up to 3 serial MRI scans as part of the research protocol.

The subgroup will be recruited from participants attending University College London and St Thomas’ Hospital only. All participants will have experienced FDCS in a previous pregnancy and will include women with and without cervical shortening in the current pregnancy based on their monitoring up to 24 weeks.

A transvaginal ultrasound using a new enhanced protocol developed by Professor Anna David at UCL will be undertaken in all women at St Thomas' Hospital. This procedure is more detailed than the standard measurement of cervical length and takes approximately 5 minutes more to perform. The site of previous scar tissue and any other abnormalities (for example the presence of cysts) will be recorded.

Serial MRIs will also be performed at St Thomas' Hospital to assess for differences in cervical anatomy as well as differences in tissue microstructure and function.

All transvaginal ultrasound and MRI imaging will occur at St Thomas' Hospital. UCL patients will have to travel to St Thomas' hospital for the ultrasounds and MRIs. These will involve extra visits although where possible these extra scans will be aligned with any routine hospital visits the patient has. Reasonable travel expenses will be reimbursed.

The groups of participants will include:
1. 30 women with a cervix >25 mm
2. 30 women with a cervix ≤25 mm (n = 15 for management with a cerclage group, n = 15 for management without a cerclage group)
The two groups will be compared and their MRI scans will be compared to their transvaginal ultrasound studies.

Any unexpected ultrasound or MRI findings will be discussed with the parents. All images will be reviewed by a specialist radiologist and a report provided to the participant and their obstetrician on the rare occasion that images reveal clinical findings which may be of significance. If any further action if deemed appropriate, this will be discussed with the mother and then organised by her obstetrician or relevant clinician. This will be stated on the patient information sheet. The participant will be offered the opportunity to withdraw from the study without this affecting their ongoing care.

The results of CRAFT-OBS and CRAFT-IMG will be published in academic journals and may be presented at national and international conferences.

Previous interventions:
The study has three overlapping components:

CRAFT-OBS:
This is a multicentre prospective cohort observational study of 2200 pregnant women with a previous history of CS in labour who will be recruited following their booking visit. Women who have had a previous FDCS and who are found to have a CL ≤25mm on transvaginal ultrasound will be offered recruitment to the CRAFT-RCT (see below). Women with a previous FDCS and a CL >25mm may be invited to participate in CRAFT-IMG.

Women will be approached by a doctor, sonographer or midwife at or following their booking appointment if they have a history of a previous emergency caesarean section. They will have until their next routine appointment to read the patient information leaflet, and if interested in taking part, consented by a member of the research team. If their hospital does clinically indicated testing with fibronectin or cervical length, the results of this data will also be collected for the study.

CRAFT-RCT:
This is an open-label, multi-centre 2 arm randomised controlled trial. Participants with a previous history of FDCS and therefore at high risk of preterm birth will be identified from their local Preterm Surveillance Clinic or through cervical length screening as advised through the March 2019 "Reducing Preterm Birth Guidelines for Commissioners and Providers."

If eligible, women will be informed by a doctor or midwife about CRAFT-RCT after their transvaginal scan confirms a cervix ≤25mm. Consent will be taken by a doctor, midwife or member of research team in clinic who is trained and familiar with the study. They will have up to 48 hours to read the patient information leaflet, and if interested in taking part, consented by a member of the research team.

This will be carried out over 30 months in at least 27 hospitals with preterm surveillance clinics (n=1000). All women with a history of FDCS will have CL monitoring as per new guidance. If their cervical length is, or becomes ≤25 mm before 24 weeks' gestation, they will be randomised (1:1) into one of two groups:
• cervical cerclage plus standard management
• standard management

Standard management involves: surveillance clinic visits in accordance with local protocols. Rescue cerclage will be offered in cases of cervical opening as per local protocols. Targeted admission for bedrest can be offered as can steroids according to clinician experience and local protocols.

Cervical length is measured routinely at participating centres for women at risk of preterm birth. It is measured using transvaginal ultrasound by a trained practitioner in accordance with local protocols when the bladder is empty. Measurements will be taken in triplicate and the shortest measurement used (as per accepted clinical protocols). When the cervical length is found to be ≤25 mm in antenatal clinic, these eligible women will be informed about the trial and have time to read the patient information leaflet. Members of the research team (midwives, doctors and scanning practitioners) will be familiar with the research and be able to discuss it with the woman.

Randomisation will be carried out online via the bespoke RedCap database. Users will be assigned a personal identifier number. Due to the nature of intervention, the study isn't blinded to the clinician or patient. Recruiters and trial coordinators will not have access to the randomisation sequence. Women will find out at the time of recruitment which arm they have been randomised to.

1. 500 women randomised to management together with a cervical cerclage. This will be booked at the time of recruitment and performed locally (according to local practice and procedures).

The vaginal cerclage will be inserted in the operating theatre by a clinician trained in the procedure (according to preferred technique of the operator) according to local protocols. It is usually inserted under regional anaesthetic. Tocolysis, antibiotics and antenatal corticosteroids can be considered at the clinician's preference, but will be documented and considered at the analysis.

Patients will have surveillance clinic visits in accordance with local protocols. Rescue cerclage will be offered in cases of cervical opening as per local guidelines. Targeted admission for bedrest and steroids when pregnancy viable will also be offered as per clinician preference. The cerclage will be removed electively at 37 weeks gestation by a trained clinician (or in the event of symptomatic preterm labour becoming established as per routine practice). The suture should also be removed if there is clinical evidence of chorioamnionitis. It is removed easily by exposing the cervix and cutting the knot, usually without the need for anaesthetic.

2. 500 women randomised to management without a cervical cerclage. This will still entail surveillance clinic visits in accordance with local protocols. Rescue cerclage will be offered in cases of cervical opening as per local protocols. Targeted admission for bedrest and steroids when pregnancy viable will also be offered.

All data capture and randomisation will occur through a bespoke RedCap database.

CRAFT-IMG:
This is a prospective sub-study collecting image data and outcomes in a sub-group of women participating in CRAFT-OBS (n=30) and CRAFT-RCT (n=30). Patients will undergo up to 3 extra transvaginal ultrasounds with up to 3 serial MRI scans as part of the research protocol.

The subgroup will be recruited from participants attending University College London and St Thomas' Hospital only. All participants will have experienced FDCS in a previous pregnancy and will include women with and without cervical shortening in the current pregnancy based on their monitoring up to 24 weeks.

A transvaginal ultrasound using a new enhanced protocol developed by Professor Anna David at UCL will be undertaken in all women at St Thomas' Hospital. This procedure is more detailed than standard measurement of cervical length and take approximately 5 minutes more to perform. The site of previous scar tissue and any other abnormalities (for example the presence of cysts) will be recorded.

Serial MRIs will also be performed at St Thomas' Hospital to assess for differences in cervical anatomy as well as differences in tissue microstructure and function.

All transvaginal ultrasound and MRI imaging will occur at St Thomas' Hospital. UCL patients will have to travel to St Thomas' hospital for the ultrasounds and MRIs. These will involve extra visits although where possible these extra scans will be alligned with any routine hospitals visits the patient has. Reasonable travel expenses will be reimbursed.

The groups of participants will include:
1. 30 women with a cervix >25 mm
2. 30 women with a cervix ≤25 mm (n=15 for management with a cerclage group, n=15 for management without a cerclage group)

The two groups will be compared and their MRI scans will be compared to their transvaginal ultrasound studies.

Any unexpected ultrasound or MRI findings will be discussed with the parents. All images will be reviewed by a specialist radiologist and a report provided to the participant and their obstetrician on rare occasion that images reveal clinical findings which may be of significance. If any further action if deemed appropriate, this will be discussed with the mother and then organised by her obstetrician or relevant clinician. This will be stated on the patient information sheet. The participant will be offered the opportunity to withdraw from the study without this effecting their ongoing care.

The results of CRAFT-OBS, CRAFT-RCT, CRAFT-IMG will be published in academic journals and may be presented at national and international conferences.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 14/12/2021:
CRAFT-OBS: Incidence of delivery <37+0 completed weeks gestation in women with a previous caesarean section in labour
CRAFT control group: Incidence of delivery <37+0 completed weeks gestation in women with a previous term vaginal birth

CRAFT-IMG: Incidence of cervical abnormalities on MRI and/or ultrasound in women who have a spontaneous preterm birth or late miscarriage with a history of a previous full dilatation caesarean section

Previous primary outcome measures:
CRAFT-OBS: Incidence of delivery <37+0 completed weeks gestation in women with a previous caesarean section in labour
CRAFT-RCT: The spontaneous preterm birth rate <34 weeks gestation between women with and women without an ultrasound indicated cerclage with a history of a full dilatation caesarean section
CRAFT-IMG: Incidence of cervical abnormalities on MRI and/or ultrasound in women who have a spontaneous preterm birth or late miscarriage with a history of a previous full dilatation caesarean section

Secondary outcome measures

Current secondary outcome measures as of 14/12/2021:
CRAFT-OBS:
1. Adverse perinatal outcome, defined as a composite outcome of death (antepartum /intrapartum stillbirths plus neonatal deaths prior to discharge from neonatal services)
2. Incidence of preterm birth <34 week gestation in women with a previous caesarean section in labour
3. Gestation at delivery stratified by the cervical dilatation at the time of previous caesarean in labour
4. Incidence of late miscarriage (14+0-23+6 weeks) in women with a previous caesarean section in labour
5. Healthcare use, e.g. the number of antenatal appointments, number of days as inpatient, cervical length, cervicovaginal fetal fibronectin levels, and number of interventions
6. Other maternal and fetal morbidities, as per COPOP core outcome set for preterm birth intervention studies:
6.1. Maternal set of outcomes:
6.1.1. Maternal mortality
6.1.2. Maternal infection or inflammation
6.1.3. Prelabor rupture of membranes
6.1.4. Harm to mother from intervention
6.2. Neonatal set of outcomes:
6.2.1. Offspring mortality
6.2.2. Offspring infection
6.2.3. Gestational age at birth
6.2.4. Harm to offspring from intervention
6.2.5. Birth weight
6.2.6. Early neurodevelopmental morbidity
6.2.7. Late neurodevelopmental morbidity
6.2.8. Gastrointestinal morbidity
6.2.9. Respiratory morbidity

CRAFT-IMG:
No secondary outcome measures

Previous secondary outcome measures as above plus:
CRAFT-RCT:
1. Adverse perinatal outcome, defined as a composite outcome of death (antepartum /intrapartum stillbirths plus neonatal deaths prior to discharge from neonatal services) or one

/more of intraventricular haemorrhage, periventricular leukomalacia, hypoxic ischaemic encephalopathy, necrotizing enterocolitis, bronchopulmonary dysplasia and sepsis.
2. Gestation at delivery
3. Late miscarriage (14+0-23+6 weeks)
4. Requirement for rescue cerclage (when fetal membranes are exposed)
5. Time between randomised intervention and delivery
6. Health costs at 28 days post-delivery

Overall study start date
11/09/2019

Completion date
01/04/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/01/2020:
All CRAFT studies:
1. Pregnant women under 24+0 weeks' gestation (or up to 36+6 weeks gestation for CRAFT-OBS) with a history of previous in-labour Caesarean section at term in any previous pregnancy
2. Ability to understand English (with or without interpreter)
3. Singleton pregnancy
4. Willing to give informed consent

CRAFT-OBS:
1. Pregnant women up until 36+6 weeks gestation who have had a previous emergency Caesarean section

CRAFT-RCT (discontinued August 2021):
1. Pregnant women between 14+0 and 23+6 weeks' gestation with a history of FDCS
2. Short cervix (< = 25mm) on transvaginal ultrasound scan

CRAFT-IMG:
1. Pregnant women between 14+0 and 23+6 weeks' gestation with a history of FDCS

Previous inclusion criteria:
All CRAFT studies:
1. Pregnant women under 24+0 weeks' gestation with a history of previous caesarean section in labour
2. Ability to understand English (with or without interpreter)
3. Singleton pregnancy
4. Willing to give informed consent

CRAFT-OBS:
1. Pregnant women 14+0-23+6 weeks gestation who have had a previous emergency Caesarean section

CRAFT-RCT:
1. Pregnant women between 14+0 and 23+6 weeks' gestation with a history of FDCS
2. Short cervix (< = 25mm) on transvaginal ultrasound scan

CRAFT-IMG:
1. Pregnant women between 14+0 and 23+6 weeks' gestation with a history of FDCS

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
4,400

Total final enrolment
6730

Key exclusion criteria
Current exclusion criteria as of 28/01/2020:
All CRAFT studies:
1. Under 16 years of age
2. Inability to give informed consent
3. Only previous caesarean section carried out before labour

CRAFT-RCT
1. Women with persistent fresh vaginal bleeding evident on speculum examination
2. Women with visible membranes evident on speculum examination or open cervix on ultrasound scan
3. Women with severe abdominal pain/evidence of sepsis (as judged by attending clinician)
4. Known significant congenital or structural or chromosomal fetal abnormality
5. Suspected or proven rupture of the fetal membranes at the time of recruitment
6. Women who have any cerclage in situ

CRAFT-IMG:
Contraindications to MRI, e.g. claustrophobia, BMI >40 kg/m2 (due to technical limitations of scanner) or a women with a non-MRI compatible metallic implant

Previous exclusion criteria:
All CRAFT studies:
1. Under 16 years of age
2. Inability to give informed consent
3. Previous caesarean section carried out before labour
4. Women recruited to studies with interventions of arabin pessary, progesterone, or cerclage, or if commenced on clinical grounds with management in the form of an arabin pessary, progesterone or cerclage will not be eligible

CRAFT-RCT
1. Women with persistent fresh vaginal bleeding evident on speculum examination
2. Women with visible membranes evident on speculum examination or open cervix on ultrasound scan
3. Women with severe abdominal pain/evidence of sepsis (as judged by attending clinician)
4. Known significant congenital or structural or chromosomal fetal abnormality
5. Suspected or proven rupture of the fetal membranes at the time of recruitment

CRAFT-IMG:
Contraindications to MRI, e.g. claustrophobia, BMI >40 kg/m2 (due to technical limitations of scanner) or a women with a non-MRI compatible metallic implant

Date of first enrolment
02/10/2019

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Hospital
Arrowe Park Road
Upton
United Kingdom
CH49 5PE

Study participating centre
Basildon and Thurrock University Hospitals NHS Foundation Trust
Basildon Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Mid Essex Hospital Services NHS Trust
Broomfield Hospital
Court Road
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital

369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Countess Of Chester Hospital NHS Foundation Trust
The Countess Of Chester Health Park
Chester
United Kingdom
CH2 1UL

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Trust HQ, PO Box 9551
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Kettering General Hospital NHS Foundation Trust
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Kingston Hospital NHS Foundation Trust
Galsworthy Road

Kingston Upon Thames
United Kingdom
KT2 7QB

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Luton and Dunstable University Hospital NHS Foundation Trust
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre
Pennine Acute Hospitals NHS Trust
Trust Headquarters
North Manchester General Hospital
Delaunays Road

Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
The Princess Alexandra Hospital NHS Trust
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
University Hospital Southampton NHS Foundation Trust
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Western Sussex Hospitals NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing

United Kingdom
BN11 2DH

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Buckinghamshire Healthcare NHS Trust
Amersham Hospital
Whielden Street
Amersham
United Kingdom
HP7 0JD

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital
Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Betsi Cadwaladr University LHB
Executive Offices
Ysbyty Gwynedd
Penrhosgarnedd

Bangor
United Kingdom
LL57 2PW

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Imperial College Healthcare NHS Trust
St Marys Hospital
Praed Street
London

United Kingdom
W2 1NY

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
York Teaching Hospital NHS Foundation Trust
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley

Camberley
United Kingdom
GU16 7UJ

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
King's College London

Sponsor details
c/o Reza Razavi
Room 5.31, James Clerk Maxwell Building
57 Waterloo Road
London
England
United Kingdom
SE1 8WA
+44 (0)2078483224
reza.razavi@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' Hospital NHS Foundation Trust

Sponsor details
c/o Elizabeth Bruna
R&D Department

16th Floor, Tower Wing
Great Maze Pond
London
England
United Kingdom
SE1 9RT
+44 (0)2071889811
R&D@gstt.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
The Jon Moulton Charity Trust (Guernsey)

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		16/11/2020	17/10/2023	Yes	No