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A pilot trial to evaluate the benefit of using ultrasound during surgical management of miscarriage

Submission date
03/05/2019

Recruitment status
No longer recruiting

Registration date
08/05/2019

Overall study status
Completed

Last Edited
22/10/2021

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

Background and study aims
Miscarriage is the failure of pregnancy before 23 weeks, which is common in early pregnancy occurring in around one in five pregnancies. Miscarriage can have a negative effect on both the physical and mental health of the woman and her partner. Sometimes it is necessary for doctors to suggest surgical treatment. Unfortunately, this can be associated with various problems such as causing a hole in the womb, infection, scarring and bleeding. This can cause problems with periods and decrease the chances of getting pregnant in the future. One of the ways that may improve gynaecological services is to increase the number of procedures performed under direct vision using hysteroscopy (a camera test which looks inside the womb), with the aim of improving treatment success rates and reducing complications. Applying similar principles to surgical treatment of miscarriage, the main aim of this study is to assess whether viewing the inside of the womb, with an ultrasound scan, during the surgical removal of the pregnancy tissue can help with the success of the procedure. The trial is also looking to see if performing the procedure in this way can reduce complications such as infection, bleeding and scarring. To answer this question a multi-centre randomised controlled study with an associated health economic evaluation is required. To ensure the feasibility of a large expensive trial it is essential to perform a pilot study. This pilot study will assess various aspects of the trial design and management and provide preliminary data that can be used to plan a substantive trial.

Who can participate?
Women aged 16 years or over who have been referred for surgical management of miscarriage.

What does the study involve?
The participants will be randomised into two separate groups. One group will undergo the surgical management of miscarriage without an ultrasound scan (standard care). The other group will undergo the surgical management of miscarriage with an ultrasound scan (study intervention). Both groups will be contacted by their clinical team over the phone 2-4 weeks following the procedure to establish whether they have developed any complications from the

procedure. The participant will attend the hospital 4-8 weeks following the procedure to undergo a hysteroscopy (a special telescope that is inserted into the womb) to investigate if they have developed any complications from the treatment.

What are the possible benefits and risks of participating?
A possible benefit from taking part in the trial is the added hysteroscopy appointment following the procedure, this can identify scar tissue in the womb, polyps or fibroids. It is thought that these abnormalities may impact future fertility. If these are found the clinician leading the participants care can discuss further management.
Scanning is widespread in the NHS and has been found to be safe. There are some minor side effects to the participants when undergoing the hysteroscopy. During the procedure the participants may get some crampy period type pains in their lower abdomen, which usually settle once treatment is completed. A small number (3 in 100) may feel faint following the procedure requiring them to lie down for few minutes until the sensation passes. Light spotting or fresh blood loss in not uncommon but again should settle within a few hours of the procedure, although some women may experience light vaginal blood loss for 2 to 3 days. Around 1 in 400 patients will get an infection that requires antibiotics. Rarely (1 in 1000), there is damage to the wall of the womb (uterine perforation).

Where is the study run from?
The study is run by the Birmingham Clinical Trials Unit based at the University of Birmingham. The participating hospital sites are:
1. Birmingham Women’s Hospital
2. University Hospital Coventry
3. St Thomas’ Hospital
(updated 30/09/2019, previously: Heartlands Hospital)

When is the study starting and how long is it expected to run for?
The study is due to start on the 1st June and will run for 10 months.

Who is funding the study?
National Institute for Health Research, UK

Who is the main contact?
1. Dr Adam Devall,
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
41001

Study information

Scientific Title
Surgical Evacuation with intraopErative Ultrasound: a pilot trial to assess feasibility

Acronym
SEE U v1.0

Study objectives
The aim of this feasibility study is to assess various aspects of the trial design and management and not to determine the relative effectiveness of intraoperative ultrasound during surgical removal of products of conception.

The feasibility study should enable us to come to one of the following conclusions:
- A substantive study is not feasible
- A substantive study is feasible with substantial modifications to the trial protocol to improve recruitment, compliance and follow-up.
- A substantive study is feasible with minor modifications to the trial protocol to improve recruitment, compliance and follow-up.
- The substantive study is feasible using the pilot protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/04/2019, West Midlands - Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; NRESCommittee.WestMidlands-Solihull@nhs.net; 0207 104 8104), ref: 19/WM/0021

Study design
Prospective pilot two arm multicentre randomised open clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy with abortive outcome

Interventions
The trial will compare surgical evacuation of products of conception with intraoperative ultrasonography versus surgical evacuation without intraoperative ultrasonography. This is a feasibility study to optimise study processes and the design of a substantive trial.

The research team will work closely with the multidisciplinary team responsible for routine patient care. The research team will consist of doctors, research nurses and research midwives. All women undergoing a routine (low risk) surgical evacuation of products of conception will be considered for the trial. Their clinical notes will be screened in order to ascertain eligibility. Only a member of the patient's existing clinical care team will have access to patient records in order to identify potential participants and check whether they meet the inclusion criteria or make the initial approach to patients. It is expected that participants will mainly be identified in the early pregnancy units after ultrasound diagnosis of miscarriage and on the emergency gynaecology wards prior to surgical management of miscarriage. The trial will be introduced through a comprehensive, evidence-based patient information sheet that will be provided prior to the procedure. Participant information sheets and consent form will be provided to each centre in English and other languages as appropriate to their local community. All participants will be approached and recruited at one of the four recruiting hospitals. A patient facing poster advertising the study will be displayed in clinically appropriate areas within the hospital.

Before the procedure, the women will be given a chance to discuss the risks and benefits of surgical evacuation with or without intraoperative ultrasonography. Written consent will then be obtained prior to randomisation.

Intervention Type
Other

Primary outcome(s)
A composite outcome of unsuccessful procedure or any of the following complications: intrauterine adhesions, infection, severe bleeding or damage to the genital tract.

Key secondary outcome(s))
Rate of individual complications; rate of serious adverse events; need for additional surgical procedure(s) for miscarriage treatment; need for medical management of miscarriage

Process outcomes:
To obtain estimates for important aspects of the protocol to allow development of a substantive trial, specifically:
1. To derive real-time data on the design aspects of the study:
1.1 Proportion of eligible women of those screened.
1.2 Proportion of eligible women randomised.
1.3 Attrition rates (proportion of women followed-up at 2 to 4 and 4 to 8 weeks)
1.4 Proportion of women switching treatments
2. To derive a realistic understanding of trial processes, in particular:
2.1 Ascertain robustness of the data collection process during and after the surgical procedure.
2.2 Determine the support required in units to ensure successful recruitment
2.3 Determine why patients decline participation or withdraw after randomisation.
3. Evaluation of acceptability to processes and intervention for patients and staff
3.1 Evaluate if outcome measurement tools and processes are acceptable and adequate.
3.2 Acceptability and impact on patients of the interventions.
3.3 Assessment of trial processes, including the choice of outcome measures and impact on staff.

Completion date
31/05/2021

Eligibility

Key inclusion criteria
1. Aged 16 years or over.
2. Referred for surgical evacuation of products of conception.
3. Willingness to be randomised between treatment modalities.
4. Willingness to undergo office hysteroscopy 4-8 weeks following surgical management of miscarriage.
5. Written informed consent obtained prior to surgical evacuation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Incomplete or retained products of conception will be excluded from the trial as there are no widely used criteria for deciding which women should have surgical evacuation
2. Suspicion of malignant gestational disease.

Date of first enrolment
02/09/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Women's Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TG

Study participating centre
St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7RH

Study participating centre
University Hospital Coventry
Clifford Bridge Road

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United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: PDF-2015-08-099

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Birmingham Clinical Trials Unit (bctu@contacts.bham.ac.uk). Anonymised IPD data will be available on request, subject to review by a data access committee. The data will be available after the publication of the primary findings and the data access committee with decide on a case by case basis for the right to access the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol file		08/03/2019	23/05/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes