

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/10/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 is 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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2. Mrs Laura Ocansey,

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Study website

<http://www.birmingham.ac.uk/seeu>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/11/2017

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

Age group

Adult

Sex

Female

Target number of participants

Planned Sample Size: 90; UK Sample Size: 90

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**

England

United Kingdom

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
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Sponsor information

Organisation
University of Birmingham

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Sponsor type
University/education

ROR
<https://ror.org/03angcq70>

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/05/2022

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 will 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?
Protocol file		08/03/2019	23/05/2019	No	No
HRA research summary			26/07/2023	No	No