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Does the removal of small submucous fibroids and endometrial polyps improve the chances of achieving a live birth in women with infertility or recurrent miscarriage?

Submission date
12/03/2021

Recruitment status
No longer recruiting

Registration date
23/03/2021

Overall study status
Completed

Last Edited
06/11/2023

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

Background and study aims
Submucous fibroids and endometrial polyps are commonly detected in women seeking treatment for infertility and recurrent miscarriage. Currently, such uterine abnormalities are routinely removed by hysteroscopic resection, but there is limited evidence to suggest that their removal improves the chances of the woman achieving a pregnancy and live birth. The trial aims to examine the clinical and cost effectiveness of hysteroscopic resection of submucous fibroids and endometrial polyps in women presenting with infertility and recurrent miscarriage.

Who can participate?
Women with a history of infertility or recurrent miscarriage with a diagnosis of submucous fibroids and/or endometerial polyps which are less than 3 cm in size.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). One group will have their fibroids of polyps removed by a procedure called hysteroscopic resection. The second group will have their fibroids or polyps left alone. Patients in both groups will continue to receive planned fertility treatments (e.g. IVF, ovulation induction, IUI, Donor Sperm Insemination, ICSI or medications such as clomid).

What are the possible benefits and risks of participating?
At present there is not enough evidence from randomised controlled trials to say whether removal of fibroids or polyps (or leaving them alone) has a negative or positive effect on pregnancy outcomes. It is the purpose of this trial to determine this.

Where is the study run from?
University of Sheffield Clinical Trials Unit (UK) and Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From April 2020 to October 2025

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
283141

Central Portfolio Management System (CPMS)
48137

Study information

Scientific Title
Hysteroscopic Excision of Leiomyoma and Polyp in Infertility (HELP Fertility?) two randomised controlled trials

Acronym
HELP Fertility?

Study objectives
To examine the clinical and cost-effectiveness of hysteroscopic removal of small (<3 cm) submucous fibroids and endometrial polyps on the chances of achieving a live birth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/02/2021, West Midlands Edgbaston (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ; +44 (0)20 7104 8112, +44 (0)207 104 8019, +44 (0)2071048089; edgbaston.rec@hra.nhs.uk), ref: 21/WM/0013

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Women with infertility or recurrent miscarriage and with a diagnosis of submucous fibroids and /or endometrial polyps

Interventions
Eligible participants will be randomised to one of two groups. One group will have their fibroids of polyps removed by a procedure called hysteroscopic resection. The second group will have their fibroids or polyps left alone. Patients in both groups will continue to receive planned fertility treatments (e.g. IVF, ovulation induction, IUI, Donor Sperm Insemination, ICSI or medications e.g. clomid).

The Sheffield Clinical Trials Research Unit (CTRU) will oversee randomisation. Participants will be allocated on a ratio of 1:1 to either receive hysteroscopic resection of the abnormalities (intervention group) or not (control group). Stratified block randomisation will be used, stratified by recruiting centre and infertility or recurrent miscarriage. The randomisation schedule will be generated by the CTRU prior to the start of the study. The randomisation sequence will be computer-generated. Block sizes will not be disclosed during the trial.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Live birth rate measured from participant records at 15 months post-randomisation

Key secondary outcome(s))
1. Live birth rate measured from participant records at 24 months post-randomisation
2. Time from randomisation to live birth measured from participant records at 15 and 24 months post-randomisation
3. Time from randomisation to pregnancy measured from participant records at 6, 15, and 24 months post-randomisation
4. Clinical pregnancy, miscarriage, and ectopic pregnancy rates measured from participant records at 6, 15, and 24 months post-randomisation
5. Incidence of premature labour, multiple births and still birth measured from participant records at 15 and 24 months post-randomisation

6. Detail of hysteroscopy received, including the number of hysteroscopic procedures received, duration of time post-surgery abstaining from sexual intercourse, and type of resection performed, collected from participant records within two weeks post-hysteroscopy
7. Patient satisfaction measured using a bespoke questionnaire at 6, 15, and 24 months post-randomisation
7. Details of fertility treatments received, including details of medications received, collected from participant records at 6, 15, and 24 months post-randomisation
8. Details of correct diagnosis/absence of abnormalities at surgery are collected from participant records within two weeks post-hysteroscopy
9. Type of submucous fibroid (type 0, 1, or 2) collected from participant records within two weeks post-hysteroscopy
10. Number of participants in the control arm who undergo resection collected from participant records at 6, 15, and 24 months post-randomisation

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. History of primary or secondary infertility. Defined as being:
1.1. Of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility
1.2. Of reproductive age who is using artificial insemination to conceive (with either partner or donor sperm) who has not conceived after 6 cycles of treatment, in the absence of any known cause of infertility)
1.3. Recurrent miscarriage (defined as the loss of two or more pregnancies before 24 weeks gestation).
2. Diagnosed endometrial polyp or submucosal fibroid ≤3 cm in size

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
35

Key exclusion criteria
1. Submucous fibroids or endometrial polyps >3 cm in size or the presence of additional medical morbidity as a result of the submucous fibroid or endometrial polyps such as anaemia due to heavy periods or significant pain which necessitates surgical intervention
2. Multiple endometrial polyps or submucous fibroids that together amass to >3 cm in total (for

example a 2.5 cm fibroid and 1 cm polyp)
3. Asherman's syndrome
4. Suspected malignancy of endometrial polyp or submucous fibroid
5. Taking part in any other interventional infertility trial
6. Pregnancy or suspected pregnancy
7. Previously randomised into another other HELP Fertility? trial

Date of first enrolment
01/04/2021

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Jessop Wing - Sheffield Teaching Hospitals
Royal Hallamshire Hospital
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current Individual participant data (IPD) sharing plan as of 06/11/2023:

Deidentified participant data and statistical code will be made available upon reasonable request. Requests should be made via email to ctru@sheffield.ac.uk, stating the data fields required and purpose of the request (ideally with a protocol but, at a minimum, with a research plan). The data dictionary and statistical analysis plan can also be made available. Requests will be considered on a case-by-case basis and requestors will be asked to complete a data sharing agreement with the sponsor before data transfer.

Previous Individual participant data (IPD) sharing plan:

The datasets generated during and/or analysed during the current study are/will be available upon request. Requests should be sent to d.a.white@sheffield.ac.uk and will be discussed at CTRU. Data will be anonymised. Participants consented to their data being anonymously shared to support other research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 6.0	26/05/2022	26/10/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes