

# 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?

<b>Submission date</b> 12/03/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/03/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2023	<b>Condition category</b> 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

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 endometrial 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 or 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?  
Dr Kirsty McKendrick, [kirsty.mckendrick@sheffield.ac.uk](mailto:kirsty.mckendrick@sheffield.ac.uk)

**Study website**  
[www.sheffield.ac.uk/scharr/research/centres/ctru/help-infertility](http://www.sheffield.ac.uk/scharr/research/centres/ctru/help-infertility)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
283141

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
CPMS 48137, IRAS 283141

## 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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Participant information sheet not yet available

**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 or 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 measure**

Live birth rate measured from participant records at 15 months post-randomisation

## **Secondary outcome measures**

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

## **Overall study start date**

01/04/2020

## **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  $\leq 3$  cm in size

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Planned Sample Size: 1120; UK Sample Size: 1120

**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**

England

United Kingdom

**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

## Sponsor details

D49, D Floor  
Royal Hallamshire Hospital  
Sheffield  
England  
United Kingdom  
S10 2JF  
+44 (0)1142265941  
angela.pinder@nhs.net

## Sponsor type

Hospital/treatment centre

## Website

<http://www.sth.nhs.uk/>

## 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

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The protocol will be published via the funder website (NETSCC-MIS).

## Intention to publish date

01/10/2026

## 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 [ctr@sheffield.ac.uk](mailto:ctr@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](mailto: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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 6.0	26/05/2022	26/10/2023	No	No