

Pilot randomised controlled trial of hysteroscopic septal resection

Submission date 06/01/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 27/01/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/08/2015	Condition category Pregnancy and Childbirth	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Women might miscarry or give birth prematurely because their wombs are divided by a wall (uterine septum). The aim in this study is to answer whether surgery to remove the wall in the womb is beneficial for women who have had miscarriages or premature babies.

Who can participate?

Women with a uterine septum, a history of miscarriage or preterm birth, or infertility.

What does the study involve?

Patients will be allocated to surgery (hysteroscopic septal resection) or no surgery. The wall in the womb can be removed or divided to make the womb normal. The surgery uses a telescope (hysteroscopy) to remove the wall.

What are the possible benefits and risks of participating?

There is some evidence to suggest that keyhole septal resection might be beneficial for women with a uterine septum and a history of miscarriage. The risk of surgery includes bleeding, infection and perforation of the womb. The complication rate for this type of procedure is about 1%.

Where is the study run from?

Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?

December 2014 to December 2017

Who is funding the study?

Nottingham University Hospitals Charity (UK)

Who is the main contact?

Dr Matthew Prior

Contact information

Type(s)

Public

Contact name

Dr Matthew Prior

Contact details

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Additional identifiers**Protocol serial number**

13GY007

Study information**Scientific Title**

Assessment of hysteroscopic metroplasty in women with a uterine septum and a history of miscarriage: a randomised controlled trial

Acronym

SEPTUM

Study objectives

Hysteroscopic septal resection in women with septate uteri and a history of miscarriage increases the proportion of women who have live births.

On 06/08/2015 the study design was changed from 'Pilot single-centre randomised controlled trial to assess feasibility for a larger adequately powered trial' to 'Pilot multi-centre randomised controlled trial to assess feasibility for a larger adequately powered trial'

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Service Committee East Midlands - Nottingham 1, 22/10/2013, 13/EM/0362

Primary study design

Interventional

Study design

Pilot multi-centre randomised controlled trial to assess feasibility for a larger adequately powered trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Women with septate uteri, a history of miscarriage or preterm birth, or infertility

Interventions

1. Hysteroscopic septal resection
2. No intervention

All patients will be followed up in the same way.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Live birth surviving until discharge from hospital

Key secondary outcome(s)

1. Uterine perforation
2. Fluid overload
3. Endometritis
4. Bleeding
5. Incomplete resection
6. Synechiae or adhesions
7. Clinical pregnancy rate
8. Miscarriage (first or second trimester)
9. Premature delivery (<34 weeks and <37 weeks)
10. Ectopic pregnancy
11. Uterine rupture
12. Delivery (vaginal, elective or emergency)
13. Post-partum haemorrhage (1500 mL)
14. Placenta praevia
15. Morbidly adherent placenta

Completion date

31/12/2017

Eligibility**Key inclusion criteria**

1. Uterine septum diagnosed with three-dimensional ultrasound
2. Aged at least 18 years old
3. Desire to conceive
4. History of one or more miscarriages (regardless of previous viable or live births)
5. No previous surgery on the uterus or endometrial cavity
6. Body-mass index of 40 kg/m² or less

Added 06/08/2015:
7. Women with infertility

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Other uterine anomalies apart from septum
2. Age younger than 18 years old
3. Not planning to become pregnant
4. Currently pregnant

Date of first enrolment

09/12/2015

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

United Kingdom

Study participating centre

Nottingham University Hospitals NHS Trust (UK)

United Kingdom

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Sponsor information

Organisation

Nottingham University Hospitals NHS Trust

ROR

<https://ror.org/05y3qh794>

Funder(s)

Funder type

Charity

Funder Name

Nottingham University Hospitals Charity (UK)

Results and Publications

Individual participant data (IPD) sharing plan

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