

# Pilot randomised controlled trial of hysteroscopic septal resection

<b>Submission date</b> 06/01/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/08/2015	<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

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**

Nurture Fertility

B Floor

East Block

Nottingham University Hospitals NHS Trust

Queen's Medical Centre Campus

Derby Road

Nottingham

United Kingdom

NG7 2UH

**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

**Study design**

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

**Primary study design**

Interventional

**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/m<sup>2</sup> 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

-

## **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?
<a href="#">HRA research summary</a>			28/06/2023	No	No