ISRCTN28960271 https://doi.org/10.1186/ISRCTN28960271

Pilot randomised controlled trial of hysteroscopic septal resection

Submission date
06/01/2015

Recruitment status
No longer recruiting

Registration date
27/01/2015

Overall study status
Completed

Last Edited
06/08/2015

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Live birth surviving until discharge from hospital

Secondary outcome measures
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

Overall study start date
09/12/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
10

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

Sponsor details
Research & Innovation Nottingham University Hospitals NHS Trust Nottingham Integrated Clinical Research Centre
C Floor
South Block Queen's Medical Centre Campus
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Charity

Funder Name
Nottingham University Hospitals Charity (UK)

Results and Publications

Publication and dissemination plan

Intention to publish date

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