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# Blind versus visual endometrial ablation: a randomised controlled trial

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 14/06/2010 | Stopped | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 29/07/2010 | Stopped | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 04/07/2016 | Urological and Genital Diseases | [_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

**Scientific Title**
Patient satisfaction, menstrual outcome and costs following blind versus visual second-generation ablation for the treatment of menorrhagia: a randomised controlled trial

**Study objectives**
Current study hypothesis as of 13/10/2011:
The aim of the study is to compare visual endometrial ablation (Hydrotheramablator) with blind endometrial ablation (Thermal balloon or Novasure Bipolar array) under general or local

anaesthesia in the postmenstrual phase in an adequately powered, double-blind, prospective randomised controlled trial. Pre-operative data, 1-year and 5-year data will be taken.

Previous study hypothesis:
The aim of the study is to compare Hydro ThermAblator (HTA) with Microwave Endometrial Ablation (MEA) under general or local anaesthesia in the postmenstrual phase in an adequately powered, double-blind, prospective randomised controlled trial. Pre-operative data, 1-year and 5-year data will be taken.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
NHS Grampian Ethics Committee - approval pending

## Primary study design
Interventional

## Study design
Double-blind randomised active-controlled parallel-group trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Women's health - reproductive disease

## Interventions
Patients will be randomised in a 1:1 basis to either blind or visual endometrial ablation performed under local or general anaesthesia in the immediate post-menstrual phase. Patients can choose their anaesthetic and will have their lining prepared by a medically induced withdrawal bleed. HTA , Thermachoice and Novasure are all NICE-approved methods of endometrial ablation and will be used within their CE mark. The duration of follow-up will be 1 year in the short term, with a follow up at 5 and 10 years to assess long-term outcomes.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
Patient satisfaction with each technique, measured using a six-point Likert scale post-operatively and at 6 and 12 months.

## Key secondary outcome(s)
1. Comparison of operative details, e.g.
1.1. Times
1.2. Difficulties
1.3. Numbers needing general anaesthetic
1.4. Acceptability of treatment measured using a six-point Likert scale post-operatively and at 6 and 12 months
1.5. Operative pain assessed by Visual Analogue Scale (VAS) and McGill Pain Questionnaire
2. Menstrual outcome

2.1. Menstrual Bleeding and Pain Scores assessed with standardised local bleeding/pain scores (0-50) and follow-up Pictorial Bleeding Assessment Chart (PBLAC) scores, at baseline, 6 and 12 months
2.2. Number of women having no periods after each procedure
3. Quality of life, measured by SF-12
4. Health service costs of Microwave Endometrial Ablation to Hydro ThermAblator ablation under general or local anaesthesia performed in the post-menstrual phase
5. Complication rates
Follow up at 5 and 10 years will assess long-term outcomes.

### Completion date
10/01/2017

### Reason abandoned (if study stopped)
Lack of funding/sponsorship

## Eligibility

### Key inclusion criteria
1. Patients eligible for endometrial ablation and be willing to be randomised to either treatment
2. Normal endometrial biopsy results
3. Uterine cavity less than 12 cm
4. Completed their family, use reliable contraception and otherwise be acceptant of hysterectomy
5. A pre-operative ultrasound scan must confirm they are suitable for either MEA or HTA
6. Pre-operative data, 1-year and 5-year data will be taken

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
1. Desire for further family
2. Abnormal endometrial pathology
3. Uterine cavity > 12 cm
4. Normal or light periods
5. Previous classical caesarean section/myomectomy/hysterotomy
6. Previous caesarean section scar less than 10 mm
7. Acute uterine infection

### Date of first enrolment
10/01/2012

**Date of final enrolment**
10/01/2017

# Locations

**Countries of recruitment**
United Kingdom

Scotland

**Study participating centre**
**Aberdeen Royal Infirmary**
Aberdeen
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AB25 2ZN

# Sponsor information

**Organisation**
NHS Grampian Endowments (UK)

**ROR**
https://ror.org/00ma0mg56

# Funder(s)

**Funder type**
Government

**Funder Name**
NHS Endowments. An application for Health Technologies Agency (HTA) funding is in progress

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration