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 04/07/2016	Condition category Urological and Genital Diseases	Individual participant data
		Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Patient satisfaction, menstrual outcome and costs following blind versus visual secondgeneration 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

Study design

Double-blind randomised active-controlled parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

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 measure

Patient satisfaction with each technique, measured using a six-point Likert scale postoperatively and at 6 and 12 months.

Secondary outcome measures

- 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.

Overall study start date

10/01/2012

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

Age group

Adult

Sex

Female

Target number of participants

220

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

Scotland

United Kingdom

Study participating centre Aberdeen Royal Infirmary

Aberdeen United Kingdom AB25 2ZN

Sponsor information

Organisation

NHS Grampian Endowments (UK)

Sponsor details

NHS Grampian Endowments,
Research & Development Department,
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Sponsor type

Government

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration