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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

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 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

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 post-operatively 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

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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