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Microwave endometrial ablation versus thermal balloon endometrial ablation - a pragmatic randomised comparison of postmenstrual treatment under general or local anaesthesia: clinical outcomes, patient acceptability and cost

Submission date
20/12/2006

Recruitment status
No longer recruiting

Registration date
21/02/2007

Overall study status
Completed

Last Edited
03/05/2011

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.abdn.ac.uk/hsru/hta/endometrial.shtml

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

Study objectives
The aim of the study is to compare Microwave Endometrial Ablation (MEA) with Thermal Balloon Endometrial Ablation (TBEA) under general or local anaesthesia in the postmenstrual phase in an adequately powered prospective randomised trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Grampian Research Ethics Committee on 24/10/2002 (ref: 02/0232)

Study design
Randomised controlled 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
Menorrhagia

Interventions
Endometrial ablation (MEA) with thermal balloon endometrial ablation (TBEA).

Microwave Endometrial Ablation
MEA uses microwave energy, which emanates from the probe tip to effectively paint the inside

of the uterus with microwave energy. The MEA causes endometrial destruction to a predictable depth through a tissue heating effect. The procedure itself lasts two to three minutes on average and utilises an 8.5 mm probe.

Thermal Balloon Endometrial Ablation
TBEA (Thermachoice, Gynecare Inc) uses a balloon that is filled with a 5% Dextrose solution that is heated to provide the Endometrial effect. It uses a 5mm catheter, which requires to be introduced into the uterus prior to inflation. The balloon probe is significantly smaller than the MEA probe and may offer advantages through reduced need for cervical dilation. Unlike the microwave technique, apart from siting the device and ensuring that normal operating pressures are achieved, there is no operator input required for the balloon treatment phase, which lasts eight minutes.

A clinical research fellow of specialist registrar level performed all procedures in theatre. All procedures were performed under general or local anaesthesia plus or minus sedation in day case theatre.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Clinical outcome using satisfaction levels and menstrual scores (including amenorrhoea rates) after each procedure.

Secondary outcome measures
1. Operative details and treatment acceptability
2. Quality of life
3. Health service costs of Microwave Endometrial Ablation to Thermal Balloon Endometrial Ablation

Overall study start date
01/01/2004

Completion date
30/04/2007

Eligibility

Key inclusion criteria
Women in the catchment area of Aberdeen Royal Infirmary with dysfunctional uterine bleeding who:
1. Have completed their family
2. Have normal endometrial pathology
3. Have a regular uterus cavity
4. Are willing to be randomised to microwave endometrial ablation or thermal balloon endometrial ablation under local anaesthesia

Participant type(s)

Patient

Age group
Not Specified

Sex
Female

Target number of participants
320

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Those who in the opinion of the attending physician are thought to have limited life expectancy (less than one year)
3. Patients who currently or have within the last three months been involved with another research project

Date of first enrolment
01/01/2004

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Gynaecology Department
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
NHS Grampian (UK)

Sponsor details
Research & Development Office
Foresterhill House Annexe

Foresterhill
Aberdeen
United Kingdom
AB25 2ZB

Sponsor type
Government

Website
http://www.nhsgrampian.org

ROR
https://ror.org/00ma0mg56

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Executive Health Department (UK) (ref: CZH/4/117)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2009		Yes	No
Other publications	cost utility analysis	01/08/2010		Yes	No