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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

Contact information

Type(s)
Scientific

Contact name
Dr Kevin Cooper

Contact details
Gynaecology Department
Ward 42
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN
+44 (0)1224 554800
Kevin.Cooper@arh.grampian.scot.nhs.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
1. Operative details and treatment acceptability
2. Quality of life
3. Health service costs of Microwave Endometrial Ablation to Thermal Balloon Endometrial Ablation

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

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
United Kingdom

Scotland

Study participating centre
Gynaecology Department
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
NHS Grampian (UK)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes