

# 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

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<b>Registration date</b> 21/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/05/2011	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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

### 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

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	01/07/2009		Yes	No
<a href="#">Other publications</a>	cost utility analysis	01/08/2010		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes