# A randomised controlled double blind trial comparing thermal balloon endometrial ablation (Cavaterm) and microwave endometrial ablation

Submission date 12/04/2005	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 13/07/2005	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 05/04/2012	<b>Condition category</b> Urological and Genital Diseases	[_] Individual participant data

#### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr Philip Kirwan

Contact details

Leicester General Hospital Gwendolen Road Leicester United Kingdom LE5 4PW +44 (0)116 258 4832 philip.kirwan@uhl-tr.nhs.uk

## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers UHL9832

#### Study information

Scientific Title

**Study objectives** Outcomes/compliance/pain following each treatment may be significantly different

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Not provided at time of registration

**Study design** Randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Not specified

**Study type(s)** Treatment

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

Health condition(s) or problem(s) studied Menorrhagia

**Interventions** Thermal Balloon Ablation versus Microwave Ablation

**Intervention Type** Other

**Phase** Not Specified

Primary outcome measure

Reduction in menstrual loss and pain

**Secondary outcome measures** Not provided at time of registration

Overall study start date 01/06/2005

Completion date 31/05/2008

## Eligibility

**Key inclusion criteria** Women with heavy menstrual bleeding due to hormonal dysfunction

Participant type(s) Patient

**Age group** Adult

**Sex** Female

**Target number of participants** 220

**Key exclusion criteria** Not provided at time of registration

Date of first enrolment 01/06/2005

Date of final enrolment 31/05/2008

#### Locations

**Countries of recruitment** England

United Kingdom

Study participating centre

**Leicester General Hospital** Leicester United Kingdom LE5 4PW

#### Sponsor information

**Organisation** University Hospitals of Leicester NHS Trust (UK)

Sponsor details Leicester General Hospital Gwendolen Road Leicester England United Kingdom LE5 4PW +44 (0)116 258 4832 philip.kirwan@uhl-tr.nhs.uk

**Sponsor type** Hospital/treatment centre

ROR https://ror.org/02fha3693

### Funder(s)

**Funder type** Government

#### Funder Name

University Hospitals of Leicester NHS Trust - an "own account" trial, funded via the NHS R&D Support Funding stream

#### **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

**IPD sharing plan summary** Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/11/2006		Yes	No