

# Hysterectomy or Endometrial Ablation Trial for Heavy menstrual bleeding

<b>Submission date</b> 27/01/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2023	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Heavy menstrual bleeding (HMB) is a very common and distressing condition which affects over 1.5 million women in the UK. It is responsible for one in 20 women consulting their general practitioner (GP) and accounts for 20% of hospital referrals in gynaecology. Initial treatment usually involves the use of drugs, including the combined oral contraceptive pill, as well as a hormone-impregnated intrauterine contraceptive device. However, these may be unsuitable or unsuccessful in some women, who will need surgical treatment. The main aim of this study is to compare the clinical and cost effectiveness of two different surgical treatments: laparoscopic supra-cervical hysterectomy (LASH) and endometrial ablation (EA) for the treatment of HMB.

### Who can participate?

Women less than 50 years of age with heavy menstrual bleeding (HMB) eligible for surgical treatment can take part.

### What does the study involve?

Eligible women will be randomly allocated to undergo either LASH or EA. All participants will be asked to complete assessment questionnaires at certain time points - before surgery and again at 6 weeks, 6 and 12 months after surgery. Women will also complete a 14-day diary immediately after their operation and a simple questionnaire at 4 weeks after surgery. Medium-term follow-up involves the completion of an additional questionnaire at 5-8 years post-randomisation (as of 15/05/2023).

### What are the possible benefits and risks of participating?

Participants may not benefit personally from taking part in the study but will be directly helping us to generate information which could help plan more effective treatment for women with heavy periods. We do not think that there are any additional risks or disadvantages to participating in this study. Whichever group participants are allocated to, their care will be overseen by an experienced consultant gynaecologist. Steps are always taken to make sure that any possible risks are minimised. As part of routine care, participants will be well informed of potential risks.

Where is the study run from?

Patients will be recruited from approximately 26 NHS hospitals in the UK:

Aberdeen Royal Infirmary, Aberdeen; Forth Valley Royal Hospital, Larbert; Countess of Chester Hospital NHS Foundation Trust, Chester; Castle Hill Hospital, Cottingham; Queen Elizabeth Hospital, Edgbaston, Birmingham; Gartnavel Royal Hospital, Glasgow; Sunderland Royal Hospital, Sunderland; The Royal Victoria Infirmary, Newcastle Upon Tyne; Harrogate District Hospital, Harrogate; Northern General Hospital, Sheffield; Worcester Royal Hospital, Worcester; Arrowse Park Hospital, Upton, Wirral; Stepping Hill Hospital, Stockport; Singleton Hospital, Swansea; Royal Cornwall Hospital, Cornwall; Queen Alexandra Hospital, Portsmouth; The Royal Hampshire County Hospital, Winchester; Whipps Cross Hospital, London; Princess Royal University Hospital, Farnborough Common, Kent; Derriford Hospital, Plymouth; The Great Western Hospital, Swindon; St Peter's Hospital, Chertsey, Surrey; Princess Anne Hospital, Southampton; Royal Sussex County Hospital, Brighton; Poole Hospital NHS Foundation Trust; Poole; Worthing Hospital, Worthing.

When is the study starting and how long is it expected to run for?

January 2014 to August 2024 (as of 15/05/2023)

Who is funding the study?

National Institute for Health Research (NIHR), UK.

Who is the main contact?

Centre for Healthcare Randomised Trials  
chart@abdn.ac.uk

### **Study website**

<https://w3.abdn.ac.uk/hsru/health/>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Siladitya Bhattacharya

### **Contact details**

School of Medicine and Dentistry  
University of Aberdeen  
Aberdeen Maternity Hospital  
2nd Floor, Foresterhill  
Aberdeen  
United Kingdom  
AB25 2ZD

-  
s.bhattacharya@abdn.ac.uk

## **Additional identifiers**

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

3/073/13

## **Study information**

### **Scientific Title**

Hysterectomy or Endometrial Ablation Trial for Heavy menstrual bleeding. A multicentre randomised controlled trial comparing laparoscopic supra-cervical hysterectomy with second generation endometrial ablation for the treatment of heavy menstrual bleeding

### **Acronym**

HEALTH

### **Study objectives**

The hypothesis being tested is that laparoscopic supra-cervical hysterectomy is superior to second generation endometrial ablation for the treatment of heavy menstrual bleeding (HMB) in terms of patient satisfaction, quality of life (QoL) and costs.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

North of Scotland Research Ethics Service Committee 2, 06/01/2014, ref. 13/NS/0155

### **Study design**

Multicentre randomised controlled 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 the contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Heavy menstrual bleeding

## Interventions

The patients are randomised to two groups.

The interventions being compared are:

1. Laparoscopic supra-cervical hysterectomy (LASH):

The LASH procedure involves removing the part of your womb that causes menstrual bleeding. This is done by keyhole surgery. Three small cuts on the stomach wall are made. The procedure is done under a general anaesthetic and patients are usually home within 24 hours of the operation. As the cervix is not removed, women still need to have cervical smears in the future.

2. Endometrial ablation (EA): The EA procedure involves placing a thin device in the womb by passing it first through the vagina and then through the cervix. The lining of the womb is destroyed and the device is then removed. EA is done as a day case procedure in hospital. It is usually done under a general anaesthetic but can be under local anaesthetic if preferred. As the uterus is not removed women still need cervical smears in the future.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome measure

1. Menorrhagia multi-attribute scale (MMAS), a condition-specific Quality of Life outcome
2. Patient satisfaction, measured on a six point scale (from totally satisfied to totally dissatisfied) measured at 12 months post surgery
3. Incremental cost (to the health service) per quality-adjusted life year (QALY) gained (LASH versus EA)

## Secondary outcome measures

Current secondary outcome measures as of 15/05/2023:

Patient-reported:

1. MMAS at 6 months and 5-8 years post-randomisation
2. Patient-reported satisfaction at 6 months and 5-8 years post-randomisation
3. Acceptability of procedure measured at 6 weeks
4. Severity of postoperative pain using a pain Numerical Rating Scale (NRS) measured at 1-14 days and at 6 weeks, symptom diary days 1 to 14 (including analgesic use)
5. Generic health-related quality of life (SF-12, EQ-5D 3-L) measured at baseline, 6 months, 12 months and 5-8 years post-randomisation
6. Sexual Activity Questionnaire (SAQ) at baseline, 6 and 12 months

Clinical

1. Duration of operation
2. Peri-operative complications and recovery details including analgesia requirements
3. Time to discharge
4. Further gynaecological surgery in 12 months and 5-8 years post-randomisation

Economic

Wider societal costs associated with changes in productivity based on information on the time taken to return to normal activities (following intervention) combined with questions on work productivity delivered during the follow-up period. Further, a simple Markov model, based on

within trial data supplemented by available published data on the requirement for further gynaecological surgery over time (following the alternative procedures) will be developed and used to extrapolate cost-effectiveness beyond 12 months.

Previous secondary outcome measures:

Patient reported:

1. MMAS at 6 months
2. Patient reported satisfaction at 6 months
3. Acceptability of procedure measured at 6 weeks
4. Severity of post operative pain using a pain Numerical Rating Scale (NRS) measured at 1-14 days and at 6 weeks, symptom diary days 1 to 14 (including analgesic use)
5. Generic health related quality of life (SF-12, EQ-5D 3-L) measured at baseline, 6 and 12 months
6. Sexual Activity Questionnaire (SAQ) at baseline, 6 and 12 months

Clinical

1. Duration of operation
2. Peri-operative complications and recovery details including analgesia requirements
3. Time to discharge
4. Further gynaecological surgery by 12 months

Economic

Wider societal costs associated with changes in productivity based on information on the time taken to return to normal activities (following intervention) combined with questions on work productivity delivered during the follow-up period. Further, a simple Markov model, based on within trial data supplemented by available published data on the requirement for further gynaecological surgery over time (following the alternative procedures) will be developed and used to extrapolate cost-effectiveness beyond 12 months.

**Overall study start date**

01/01/2014

**Completion date**

31/08/2024

## Eligibility

**Key inclusion criteria**

1. Women less than 50 years of age with heavy menstrual bleeding eligible for endometrial ablation
2. Women who are willing to be randomised between laparoscopic supra-cervical hysterectomy and endometrial ablation

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

648

**Total final enrolment**

660

**Key exclusion criteria**

1. Women with plans to conceive, endometrial atypia, uterine cavity size greater than 11 cm, submucosal fibroids distorting the uterine cavity, contradictions for laparoscopic surgery (e.g. midline lower abdominal incision or known intrabdominal / pelvic adhesions) and previous endometrial ablation (EA)
2. Women who are unable to give informed consent or complete trial documentation

**Date of first enrolment**

01/01/2014

**Date of final enrolment**

31/03/2017

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

School of Medicine and Dentistry

Aberdeen

United Kingdom

AB25 2ZD

**Sponsor information****Organisation**

University of Aberdeen/NHS Grampian (UK)

**Sponsor details**

Research and Development Office

Foresterhill House Annexe

Foresterhill

Aberdeen

Scotland

United Kingdom

AB25 2ZB

## Sponsor type

University/education

## ROR

<https://ror.org/016476m91>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research (NIHR) (UK) - NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) - NIHR Health Technology Assessment Programme (HTA), ref: 12/35/23

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

01/09/2019

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Chief Investigator, Prof Siladitya Bhattacharya, s.bhattacharya@abdn.ac.uk.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	19/10/2019	17/09/2019	Yes	No
<a href="#">Results article</a>	results	01/09/2019	03/10/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No