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Hysterectomy or Endometrial AbLation Trial for Heavy menstrual bleeding

Submission date
27/01/2014

Recruitment status
No longer recruiting

Registration date
28/01/2014

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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; Arrowe 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

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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
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United Kingdom
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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?
Results article	results	19/10/2019	17/09/2019	Yes	No
Results article	results	01/09/2019	03/10/2019	Yes	No
HRA research summary			28/06/2023	No	No