ISRCTN73816767 https://doi.org/10.1186/ISRCTN73816767

A randomised controlled trial of day-care versus outpatient thermal balloon endometrial ablation using Thermachoice

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 06/10/2009	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr F A Marsh

Contact details
Academic Unit of Obstetrics and Gynaecology
Gledhow Wing
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0)787 946 3287 and 65485
r&d@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436130477

Study information

Scientific Title

Study objectives
The safety and efficacy of thermal balloon endometrial ablation (EA) for the treatment of menorrhagia is well established. However the vast majority have been performed under general anaesthetic with its resultant risk and costs. Thermachoice has been performed in the outpatient setting both in this hospital and several others around the UK. The potential advantages of performing this technique in the outpatient setting are:
- The avoidance of general anaesthesia and its associated risks
- Earlier discharge from hospital
- Faster return to full mobility and fitness
- Less time of work
- Less cost to the patient

We plan to undertake a randomised controlled trial in order to compare out-patient (OP) and day-care (DC) Thermachoice. We will determine the acceptability, recovery and cost of both procedures. Longer term follow up will be undertaken with validated questionnaires comparing patients' menstrual symptoms before and after the treatment. We hypothesise that Thermachoice in the outpatient setting is a safe, acceptable treatment for menorrhagia.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Menorrhagia

Interventions
Patient will be randomised to
1. Day care group
2. Outpatient group

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patient satisfaction and acceptability with the two procedures

Secondary outcome measures
To analyse and compare the two procedures in relation to:
1. Speed of recovery
2. Time away from home
3. Time away from work
4. Patient satisfaction at 6 and 12 months
5. Symptomatic changes specially menorrhagia severity and other menstrual symptoms e.g. dysmenorrhea at 6 and 12 months.
6. Cost to the patient, employer and NHS.
7. Health related quality of life changes at 6 and 12 months.

Overall study start date
01/01/2003

Completion date
01/06/2004

Eligibility

Key inclusion criteria
Patients will be recruited from the outpatient Gynaecology and Hysterscopy clinics.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
73 (added 06/10/09)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2003

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Obstetrics and Gynaecology
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/03/2007		Yes	No