

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

Registration date
30/09/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
06/10/2009

Condition category
Urological and Genital Diseases

☐ 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

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 Hysteroscopy 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