

Microwave endometrial ablation without endometrial preparation in the outpatient setting

Submission date
18/11/2009

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
25/11/2009

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
13/02/2013

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

Contact name

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Additional identifiers

Protocol serial number

CSO - CZH/4/21

Study information

Scientific Title

The effects of hormonal endometrial preparation before microwave endometrial ablation: patient acceptability, treatment outcomes and costs - a single centre unblinded randomised controlled trial

Study objectives

Is microwave ablation outcome affected by undertaking without endometrial preparation and in an outpatient setting? A randomised trial comparing it to traditional preparation and treatment in operating theatre.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Grampian Research Ethics Committee approved on the 3rd August 2000 (ref: 00/0023)

Study design

Single centre unblinded randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Menorrhagia

Interventions

Trial arm one: microwave endometrial ablation (MEA) 4 weeks after endometrial preparation with danazol or GnRH analogue in theatre setting

Trial arm two: MEA out-patient setting 5 to 7 days after start of period

All under local anaesthetic. There is a baseline assessment of menstrual dysfunction and quality of life. Operative outcomes, discomfort, analgesic requirements and acceptability are all measured. Follow up at one year and five years to determine satisfaction with treatment, quality of life (SF-36), menstrual outcomes and costs. All by postal questionnaires.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Patient acceptability

Key secondary outcome(s)

Measured immediately-post procedure and at 1 year and 5 years:

1. Menstrual outcomes
2. Quality of life
3. Costs

Completion date

31/03/2003

Eligibility

Key inclusion criteria

1. Women aged 30 to 55 years
2. Suitable for endometrial ablation as treatment for heavy periods
3. Premenopausal
4. Not planning to have any (further) children

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Unsuitable for endometrial ablation
2. Unwilling to have procedure under local anaesthetic
3. Allergic to local anaesthetic agents

Date of first enrolment

01/04/2001

Date of final enrolment

31/03/2003

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Ward 42, Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
NHS Grampian (UK)

ROR
<https://ror.org/00ma0mg56>

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK)

Results and Publications

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	01/08/2005		Yes	No
Results article	results	01/03/2010		Yes	No