Microwave endometrial ablation without endometrial preparation in the outpatient setting

Submission date	Recruitment status	Prospectively registered		
18/11/2009	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/11/2009	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
13/02/2013	Urological and Genital Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Patient acceptability

Secondary outcome measures

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

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

Overall study start date

01/04/2001

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

Age group

Adult

Sex

Female

Target number of participants

210

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

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Ward 42, Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation

NHS Grampian (UK)

Sponsor details

Asgrove House Foresterhill Site Aberdeen United Kingdom AB25 2ZN susan.ingram@nhs.net

Sponsor type

Government

Website

http://www.nhsgrampian.org/

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

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