ISRCTN95516133 https://doi.org/10.1186/ISRCTN95516133

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

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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

31/03/2003

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
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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