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A randomised comparison of microwave endometrial ablation with transcervical resection of the endometrium: follow-up at a minimum of ten years

Submission date 06/10/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/12/2008	**Overall study status** Completed	
Last Edited 10/12/2008	**Condition category** 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
06/S0801/123

Study information

Scientific Title

Acronym
MEA vsTCRE

Study objectives
To compare outcomes and further operations at a minimum of ten years following microwave endometrial ablation (MEA™) or transcervical resection of the endometrium (TCRE).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Original study: Grampian Health Board Joint Ethical Committee, approved on 11/12/1995 (Project no.: 2459)
Follow-up study: Grampian Local Research Ethics Committee, approved on 05/02/2007 (ref: 06 /S0801/123)

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
Heavy menstrual bleeding

Interventions
Interventions:
Microwave endometrial ablation (MEA™) vs transcervical resection of the endometrium (TCRE).

Start date of RCT: 11/12/1995
End date of RCT: 01/12/1998 (end of follow-up)

Follow-up study: postal questionnaires and operative databank review.

Start date of the follow-up study: 01/03/2007
End date of the follow-up study: 01/10/2008

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient satisfaction and acceptability of treatment, assessed by questionnaires (Timepoints: T1-T5).

Timepoints:
T0: Within 6 weeks after operation
T1: 4 months after operation
T2: 12 months after operation
T3: Minimum of 2 years after operation
T4: Minimum of 5 years after operation
T5: Minimum of 10 years after operation

Additional data were also obtained via a hospital database.

Secondary outcome measures
The following were assessed at timepoints T0-T5:
1. Menstrual symptoms (questionnaires)
2. Changes in health related quality of life, assessed by the SF-36 Health Survey
3. Additional treatments received (questionnaires)

Timepoints:
T0: Within 6 weeks after operation
T1: 4 months after operation
T2: 12 months after operation
T3: Minimum of 2 years after operation
T4: Minimum of 5 years after operation
T5: Minimum of 10 years after operation

Additional data were also obtained via a hospital database.

Overall study start date
11/12/1995

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Premenopausal women, no age limits
2. Heavy menstrual loss
3. Family was complete (i.e. no desire for further children)

4. No endometrial atypia
5. Uterine size not greater than ten weeks size

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
263

Key exclusion criteria
Unwilling to complete follow-up

Date of first enrolment
11/12/1995

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ward 42
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
NHS Grampian (UK)

Sponsor details
Aberdeen Royal Infirmary
Foresterhill

Aberdeen
United Kingdom
AB25 2ZN

Sponsor type
Government

Website
http://www.nhsgrampian.org

ROR
https://ror.org/00ma0mg56

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Aberdeen Royal Infirmary, Gynaecological Endoscopy Research Fund (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	Original trial results	27/11/1999		Yes	No
Results article	Two-year follow-up results	01/06/2002		Yes	No
Results article	Five-year follow-up results	01/04/2005		Yes	No