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# 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

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |