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A randomised controlled trial of outpatient hysteroscopy looking at the effects of temperature and pressure

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/10/2017	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Adam L Magos

Contact details
University Department Of Obstetrics and Gynaecology
Royal Free Hampstead NHS Trust
Pond Street
Hampstead
London
United Kingdom
NW3 2QG

Additional identifiers

Protocol serial number
N0256159467

Study information

Scientific Title

A randomised controlled trial of outpatient hysteroscopy looking at the effects of temperature and pressure

Study objectives
To determine whether women who undergo hysteroscopy experience more discomfort when there is a change in pressure and temperature of the saline used to distend the endometrial cavity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Surgery: Hysteroscopy

Interventions
Randomised controlled trial:
1. Normal saline, 37degree celsius, 150 mmHg
2. Normal saline, room temperature 100mmHg
3. Normal saline, room temperature, 200 mmHg
4. Saline, room temperature, 150 mmHg

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Service outcome development

Key secondary outcome(s)
Not provided at time of registration

Completion date
15/07/2004

Eligibility

Key inclusion criteria
120 patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
15/07/2003

Date of final enrolment
15/07/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Department Of Obstetrics and Gynaecology
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Free Hampstead NHS Trust (UK) NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration