ISRCTN62284430 https://doi.org/10.1186/ISRCTN62284430

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure
Service outcome development

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/07/2003

Completion date
15/07/2004

Eligibility

Key inclusion criteria
120 patients

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

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
England

United Kingdom

Study participating centre

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

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

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