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Prospective randomised controlled trial of room temperature versus body temperature saline in outpatients hysteroscopy and pain scores

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 18/10/2017	**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

N0155126389

Study information

Scientific Title
Prospective randomised controlled trial of room temperature versus body temperature saline in outpatients hysteroscopy and pain scores

Study objectives
Comparison of body temperature saline versus room temperature saline in outpatient hysteroscopy. Assessment of procedural discomfort using pain scores.

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
Urological and Genital Diseases: Hysteroscopy

Interventions
This is a pilot study comparing discomfort levels in two groups of patients undergoing hysteroscopy.
In the one group, hysteroscopy will be performed in the clinic using room temperature saline to distend the uterine cavity (the existing method in use).
In the second group saline warmed to body temperature is used.
Discomfort levels are assessed in the two groups using pain scores.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
30/07/2004

Eligibility

Key inclusion criteria
50 outpatients

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
50

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2004

Date of final enrolment
30/07/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Obstetrics and Gynaecology
Manchester
United Kingdom
M8 5RB

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pennine Acute Hospitals NHS Trust (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