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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

Protocol serial number
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

Study type(s)
Other

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(s)
Not provided at time of registration

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

Completion date
30/07/2004

Eligibility

Key inclusion criteria
50 outpatients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pennine Acute Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration