

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/10/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes