

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/10/2017	<b>Condition category</b> 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

### Contact name

Dr Adam L Magos

### Contact details

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Royal Free Hampstead NHS Trust  
Pond Street  
Hampstead  
London  
United Kingdom  
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## 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