

# A prospective randomised controlled trial of traditional hysteroscopy or "no touch" hysteroscopy comparing patient discomfort and time taken to perform each procedure

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/07/2009	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**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

N0256130918

# Study information

## Scientific Title

## Study objectives

To determine whether women who undergo traditional hysteroscopy experience more discomfort during hysteroscopy compared to women who undergo no touch hysteroscopy

## 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)

Diagnostic

## Participant information sheet

## Health condition(s) or problem(s) studied

Not Applicable: Hysteroscopy

## Interventions

Women were randomised to undergo either traditional saline hysteroscopy requiring the use of a speculum and tenaculum, or a 'no-touch' vaginoscopic hysteroscopy which does not require a speculum or tenaculum. Each group was further subdivided to have hysteroscopy with either a 2.9-mm or 4-mm hysteroscope. Patients were asked to complete pre- and postprocedure questionnaires ranking pain scores.

## Intervention Type

Other

## Phase

Not Applicable

**Primary outcome measure**

Service outcome development

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

21/10/2003

**Completion date**

31/10/2004

## **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**

21/10/2003

**Date of final enrolment**

31/10/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University Department of Obstetrics & Gynaecology**  
London  
United Kingdom  
NW3 2QG

## **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**

The Royal Free Hampstead 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2005		Yes	No