

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

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Diagnostic

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(s)

Service outcome development

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/2004

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

21/10/2003

Date of final enrolment

31/10/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University Department of Obstetrics & 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)

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?
Results article	results	01/07/2005		Yes	No