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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

Registration date
30/09/2004

Last Edited
13/07/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study design
Randomised controlled trial

Primary study design
Interventional

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