ISRCTN49078427 https://doi.org/10.1186/ISRCTN49078427

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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
13/07/2009

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

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?
Results article	results	01/07/2005		Yes	No