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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
30/09/2004		Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
<b>Last Edited</b> 13/07/2009	<b>Condition category</b> Other	[] Individual participant data		

## 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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# 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