

# Optimum intrauterine filling pressures needed to perform outpatient diagnostic hysteroscopy

<b>Submission date</b> 02/12/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/12/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/03/2016	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Outpatient diagnostic hysteroscopy is an endoscopic examination of the inside of the womb. In order to visualise inside the womb, a clear fluid is usually administered under pressure (100 mmHg) to distend the cavity of the womb. This study aims to establish if lower filling pressures can be used to visualise inside the womb and whether this may reduce the level of pain the woman experiences.

### Who can participate?

All women who are due to undergo an outpatient hysteroscopy procedure in Gynaecology Outpatients Department of the University College London Hospitals (UK) and are able to give informed consent are invited to take part in this trial.

### What does the study involve?

The women will be randomly allocated to three different level of filling pressure (100, 70 or 40 mmHg) and they and the assessor will not know which pressure level is used (this is called blinding). The assessor will judge whether the visualisation was adequate or inadequate and the woman will be asked to score the level of pain she experienced during the procedure. If the visualisation is inadequate, then the standard filling pressure of 100 mmHg will be used to complete the procedure.

### What are the possible benefits and risks of participating?

There are no additional risks. The only risks involved will of those related to the outpatient hysteroscopy procedure itself. They include infection, bleeding and uterine perforation (making a hole in the wall of the womb) and are very rare.

### Where is the study run from?

The study is carried out at the Gynaecology Outpatients Department of the University College London Hospitals (UK).

### When is the study starting and how long is it expected to run for?

The study started in March 2007. We aim to recruit 230 women in total and we anticipate that the recruitment will be completed in early 2012.

Who is funding the study?

The study is sponsored by the University College London Hospitals NHS Foundation Trust (UK).

Who is the main contact?

Mr Ertan Saridogan, Consultant Gynaecologist

ertan.saridogan@uclh.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

Mr Ertan Saridogan

### Contact details

Women's Health Division

University College London Hospitals

250 Euston Road

London

United Kingdom

NW1 2PG

+44 20 3447 9759

ertan.saridogan@uclh.nhs.uk

## Additional identifiers

### Protocol serial number

06/0112

## Study information

### Scientific Title

Optimum intrauterine filling pressures needed to perform outpatient diagnostic hysteroscopy: a double-blind randomised trial

### Study objectives

The filling pressures used to perform outpatient diagnostic hysteroscopy can be reduced without compromising the visualisation of uterine cavity and this may reduce the pain experienced by the woman

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The Joint UCL/UCLH Committes on the Ethics of Human Research, 28 September 2006, ref: 06/Q0502/69

### Study design

Double blind randomised trial

## **Primary study design**

Interventional

## **Study type(s)**

Diagnostic

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

Hysteroscopy

## **Interventions**

Women who are due to undergo an outpatient hysteroscopy procedure will be recruited after obtaining informed consent. They will be allocated to one of the three pressure groups (100mmHg, 70mmHg or 40mmHg) using computer generated random numbers sealed in an opaque envelope which is opened by the attending nurse or healthcare assistant who sets up the pressure of distension medium. The woman and the operator will be blinded to the allocated pressure. The hysteroscopy procedure will be performed by an experienced operator who will judge whether the uterine distension is adequate or inadequate. At this point the women will be asked to report her pain score between 0 to 10, using a Visual Analogue Scale. If the visualisation of the uterine cavity is inadequate, the operator will then ask the nurse/healthcare assistant to establish the pressure to 100 mmHg, which is the standard distension pressure used in the department to complete the procedure. Any additional necessary procedures such as biopsy, polyp or fibroid removal will be carried out after the assessment of the operator and the woman.

## **Intervention Type**

Procedure/Surgery

## **Phase**

Not Applicable

## **Primary outcome(s)**

Adequate visualisation of the uterine cavity assessed at the same point when the operator judges whether the visualisation is adequate or inadequate

## **Key secondary outcome(s)**

Visual Analogue Score (VAS) pain score assessed at the same point when the operator judges whether the visualisation is adequate or inadequate

## **Completion date**

31/03/2012

# **Eligibility**

## **Key inclusion criteria**

1. Women who are referred for an outpatient hysteroscopy procedure at the University College London Hospitals
2. Those who give informed consent to participate in the trial

## **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Women who are unable to communicate in English
2. Those who are not suitable for an outpatient hysteroscopy (i.e active pelvic infection, possibility of pregnancy, unusually anxious women)

**Date of first enrolment**

01/03/2007

**Date of final enrolment**

31/03/2012

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Women's Health Division**

London

United Kingdom

NW1 2PG

## **Sponsor information**

**Organisation**

University College London Hospitals NHS Foundation Trust (UK)

**ROR**

<https://ror.org/042fqyp44>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

University College London Hospitals NHS Foundation 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?
<a href="#">Results article</a>	results	01/01/2014		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes