ISRCTN78400671 https://doi.org/10.1186/ISRCTN78400671

Optimum intrauterine filling pressures needed to perform outpatient diagnostic hysteroscopy

Submission date
02/12/2011

Recruitment status
No longer recruiting

Registration date
19/12/2011

Overall study status
Completed

Last Edited
16/03/2016

Condition category
Surgery

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information leaflet

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

Secondary outcome measures

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

Overall study start date
01/03/2007

Completion date
31/03/2012

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
230 women

Key exclusion criteria
1. Women who are unable to communicate in English
2. Those whoe 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
England

United Kingdom

Study participating centre

Women's Health Division
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
250 Euston Road
London
England
United Kingdom
NW1 2PG
+44 (0)20 3456 7890
ertan.saridogan@uclh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uclh.org/

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

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	01/01/2014		Yes	No