

Pain assessment during outpatient hysteroscopy using room temperature versus warm normal saline as distention medium.

Submission date 22/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/07/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A hysteroscopy is a procedure used to examine the inside of the uterus. It is an established diagnostic tool. One of the main causes of procedure failure is patient discomfort and pain. We do not know what the best way of reducing pain is. The aim of this study is to compare a warm normal saline distension solution versus a standard room-temperature normal saline.

Who can participate?

Women referred for outpatient hysteroscopy between January 2013 and June 2015.

What does the study involve?

Participants are allocated to one of two groups: one group receiving a sterile 0.9% normal saline warmed up to 32 degrees C as distention medium or another group receiving a room temperature sterile 0.9% normal saline solution. No pre medication or anaesthetics procedure used.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Central Clinical Hospital of Ministry of the Interior in Warsaw (CSK MSW) Department Obstetrics and Gynaecology (Poland)

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

January 2015 to July 2015

Who is funding the study?

Central Clinical Hospital of Ministry of the Interior in Warsaw (CSK MSW) Department Obstetrics and Gynaecology (Poland)

Who is the main contact?

Tadeusz Issat

Contact information

Type(s)

Scientific

Contact name

Mr Tadeusz Issat

Contact details

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Poland
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A prospective randomized study for pain assessment during outpatient hysteroscopy using room temperature versus warm normal saline as distention medium.

Study objectives

To assess the efficacy of warm normal saline distension solution versus a standard, room-temperature normal saline as distension medium for the pain relief during outpatient hysteroscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Board and Control of Research trials on Humans and Animals in CSK MSW Warsaw, 01/07/2012, ref 73/2012

Study design

Prospective randomized single center trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Outpatient hysteroscopy

Interventions

Office hysteroscopy with warm normal saline distension solution or a standard room temperature normal saline distension medium

Intervention Type

Procedure/Surgery

Primary outcome measure

Visual analogue scale (VAS) score during, 5 minutes and 15 minutes after the procedure. Median VAS scores during and directly after the anaesthesia-free hysteroscopy.

Secondary outcome measures

Side effects, complications failure rate, procedure time and the pain level during each stage of procedure.

Overall study start date

01/01/2014

Completion date

31/07/2015

Eligibility**Key inclusion criteria**

All patients aged over 18 years referred for hysteroscopy for diagnosis of abnormal endometrium on ultrasound, endometrial polyps and uterine bleeding were included in the study. All participants had a pelvic ultrasound examination to confirm the initial diagnosis.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

100

Key exclusion criteria

Women with a possible pregnancy, lower genital tract infections, gestational trophoblastic disease, presence of endocervical polyps visualized on a speculum examination, asthma, acute porphyria, hepatitis, renal failure, lactation and oversensitivity to one of the agents or their elements were excluded.

Patients with endometrial polyps measuring more than 30mm were excluded and referred for operative hysteroscopy under anesthesia.

Date of first enrolment

01/01/2015

Date of final enrolment

20/06/2015

Locations**Countries of recruitment**

Poland

Study participating centre

Central Clinical Hospital of Ministry of the Interior in Warsaw (CSK MSW) Department Obs and Gyn

Warsaw

Poland

02-507

Sponsor information**Organisation**

Central Clinical Hospital of Ministry of the Interior in Warsaw (CSK MSW) Department Obs and Gyn

Sponsor details

Department of Obstetrics and Gynaecology

Woloska 137

Warsaw

Poland
02/507

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03b45mr48>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Central Clinical Hospital of Ministry of the Interior in Warsaw (CSK MSW) Department Obs and Gyn

Results and Publications

Publication and dissemination plan

Publication in peer reviewed journal focused on minimally invasive gynaecology. Publication of the results and conclusion after finalizing the analysis in around 2 months.

Intention to publish date

31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available