ISRCTN56764412 https://doi.org/10.1186/ISRCTN56764412

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

Registration date
24/07/2015

Overall study status
Completed

Last Edited
24/07/2015

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
CSK MSW, Woloska 137,
Warsaw
Poland
02-507

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