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Gel instillation sonohysterography (GIS) using Endosgel versus ExEmgel, comparison of pain and image quality (Gel contrast echoscopie gebruikmakende van Endosgel versus ExEmgel, vergelijking van pijn en beeldkwaliteit)

Submission date
19/02/2014

Recruitment status
No longer recruiting

Registration date
14/07/2014

Overall study status
Completed

Last Edited
14/07/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Saline infusion sonohysterography is an accurate ultrasound procedure that allows health care professionals to look at the inside of the uterus (endometrial cavity) and the uterus lining (endometrium). They are used for a number of reasons, including looking for polyps, investigating the reasons for postmenopausal (after the menopause) bleeding and looking at the shape of the endometrial cavity (this can be useful in investigating problems such as multiple miscarriages or infertility). It is a simple procedure often done in outpatient clinics, but it can be uncomfortable due to leaking of the saline during the test. Gel is now often used instead, as it is thought that using a gel (gel infusion sonohysterography) is less painful than saline and that it produces clearer images and allows for 3D sonography (for example, 3D ultrasound). A number of gels are available, some containing pure hydroxyethyl glycerin, others containing small amount of chlorhexidine with or without lidocaine. This may be important, as different gels may affect how painful the procedure is, cause different side effects and affect the quality of the image made, but there is, as yet, no published data on this. We suggest that a sonohysterography using gel that contains small amounts of chlorhexidine will be more painful than if a gel containing pure hydroxyethyl glycerine is used, but the resulting images produced will be of equal quality. The main purpose of this study is to compare two types of gel, Endosgel (which contains chlorhexidine) and ExEmgel (containing hydroxyethylcellulose and glycerol)

Who can participate?
Women aged between 20-80 years, suffering from either abnormal bleeding from the uterus or infertility believed to be due to an abnormality of the uterus and planned for a gel infusion sonohysterography (GIS).

What does the study involve?
Patients are randomly allocated into one of two groups. One group has GIS using Endosgel and

the other group ExEmgel. Patients report on any pain felt during the procedure and the quality of the images obtained compared. Patients are then called by telephone to talk again about any pain experienced 3 weeks and then 3 months after the GIS

What are the possible benefits and risks of participating?
Both gels are used routinely and, in general, are well-tolerated and safe. Some discomfort may be felt by patients during the procedure.

Where is the study run from?
The VU University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
September 2012 to March 2014

Who is funding the study?
1. Dutch Ministry of Education, Culture and Science (Netherlands)
2. VU University Medical Center (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34744

Study information

Scientific Title
Gel instillation sonohysterography (GIS) using Endosgel versus ExEmgel, comparison of pain and image quality

Acronym
GISPAIN (Gel Insillation Sonography and PAIN scores)

Study objectives
The purpose of this study is to compare two types of gel, Endosgel and ExEmgel, during gel instillation sonohysterography with respect to patients pain perception and image quality. We hypothesize that gel including small amounts of chlorhexidine induces more pain compared to pure hydroxethyl glycerin gel.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Review Committee VU University Medical Center (Medisch Etische Toetsingscommissie Vrije Universiteit medisch centrum), 09/03/2012, ref. 2011/36

Study design
Single-centre randomised controlled trial, blinded for the patient and examiners of the saved 3D images with respect to used type of gel (double-blind)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
https://dl.dropboxusercontent.com/u/53686439/PatientenbriefCPM8metVerzekeringsbijlage.pdf

Health condition(s) or problem(s) studied
Healthy participants with abnormal uterine bleeding or infertility and suspected for having a intrauterine abnormality

Interventions
Intervention group: The use of ExEmgel.
Control group: The use of Endosgel.
Both gels are used in daily practice (in the VU University Medical Center [VUmc]) during GIS.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
AUC of continuous registered pain score (continuous VAS) during gel installation and following sonography.

Secondary outcome measures
1. Pain score (AUC using continuous pain registration) of the entire procedure and of specific parts of the procedure
2. Subjective reported VAS score
3. Image quality
Various prognostic factors will be registered.

Overall study start date
01/09/2012

Completion date
01/03/2014

Eligibility

Key inclusion criteria
1. Woman with abnormal uterine bleeding or infertility and suspected for having an intrauterine abnormality
2. Age 20-80 yr

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
70

Key exclusion criteria
1. Pregnancy or premenopausal women in the luteal phase without use of contraception
2. Pelvic Inflammatory Disease (PID)
3. Risk of malignancy
4. Contraindication for the use of NSAIDS
5. Known allergy for chlorhexidine
6. Inability to understand Dutch or English

Date of first enrolment

01/09/2012

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Boelelaan 1117
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Sponsor information

Organisation
VU University Medical Center (Netherlands)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name

Dutch Ministry of Education, Culture and Science (Netherlands)

Funder Name
VU University Medical Center (Netherlands)

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