

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/07/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/07/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Amsterdam

Netherlands

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Sponsor information

Organisation

VU University Medical Center (Netherlands)

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes