

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

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The objectives of this trial are:- To compare experienced pain during GIS using ExEmgel versus Endosgel (continuous measure pain and subjective reported VAS score)- To compare the image quality, including the occurrence of air bubbles during both...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Reproductive tract disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38342

### Source

ToetsingOnline

### Brief title

GISPAIN

### Condition

- Reproductive tract disorders NEC

### Synonym

intra-uterine abnormalities, polyp, submucous fibroid

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** - Gel instillation sonohysterography -- Continuous Real time Pain Measurement, - Image quality, - Pain

## Outcome measures

### Primary outcome

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

### Secondary outcome

Other outcome parameters are pain score (AUC using continuous pain registration) of the entire procedure and of specific parts of the procedure, subjective reported VAS score and image quality. Various prognostic factors will be registered.

## Study description

### Background summary

Sonohysterography using Saline or Gel has proven to be a very accurate diagnostic method for the evaluation of intra-uterine disorders. Various gels can be used during Gel installation Sonography (GIS). Some contain pure hydroxyethyl glycerin, others contain small amount of chloorhexidine with or without lidocaine. Although the gel content may effect pain perception, side effects and imaging abilities, comparative studies have not been published yet. We hypothesize that gel including small amounts of chloorhexidine induces more pain compared to pure hydroxethyl glycerin gel.

The purpose of this study is, to compare two types of gel; Endosgel en ExEmgel with respect to patients pain perception and image quality.

### Study objective

The objectives of this trial are:

- To compare experienced pain during GIS using ExEmgel versus Endosgel (continuous measure pain and subjective reported VAS score)

- To compare the image quality, including the occurrence of air bubbles during both procedures (real time and retrospective during evaluation of the 3D images).

## **Study design**

The study will be a randomised controlled trial, blinded for the patient and examiners of the saved 3D images with respect to used type of gel.

## **Intervention**

Intervention group: The use of ExEmgel.

Control group: The use of Endosgel.

Both gels are used in daily practice (in the VUmc) during GIS.

## **Study burden and risks**

Risks and burden are linked to the protocol procedures. Although these are routine procedures, carried out by medically qualified personnel, they may cause some discomfort and temporary pain to the subjects. However, these procedures are general well-tolerated and safe. The extra burden of participation in the study is little and is limited to answering a couple of questions with regard to history and complaints, to operate the continuous painmeter during the whole procedure, and responding to three short questionnaires directly, 3 weeks and 3 months after the procedure. The total burden in time is at maximum 15 minutes.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- woman with abnormal uterine bleeding or infertility and suspected for having an intrauterine abnormality
- Age 20-80 yr

### Exclusion criteria

- Pregnancy or premenopausal women in the luteal phase without use of contraception
- Pelvic Inflammatory Disease (PID)
- Risk of malignancy
- Contraindication for the use of NSAIDS
- Known allergy for chloorhexidine
- Inability to understand Dutch or English

## Study design

### Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Diagnostic

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-09-2012
Enrollment:	70
Type:	Actual

## Medical products/devices used

Generic name:	Endosgel en ExEmgel
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	07-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register**

CCMO

**ID**

NL34744.029.11

## Study results

Date completed: 10-02-2014

Actual enrolment: 75