Hysmis study.
Misoprostol for cervical priming prior to hysteroscopy in postmenopausal or nulliparous women; a multi-centre randomised placebo controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22053

Source
NTR

Brief title
Hysmis

Health condition

Hysteroscopy/hysteroscopie
Pain/pijn
Misoprostol

Sponsors and support

Primary sponsor: VUmc
Source(s) of monetary or material Support: Sponsor initiated

Intervention

Outcome measures

Primary outcome

Pain measured by a continuous pain score meter

Secondary outcome

the postoperative pain measured directly after the procedure measured as VAS-score by questionnaire (questionnaire nr 3)
the pain during passage of the cervix measured as the Peak Pain Score (PPS) and the Average Pain per Second (APS)
the total experienced pain during the procedure measured as AUC and PPS
the level of difficulty of the hysteroscopy experienced by the surgeon, measured by a Likert 5-point Scale
the total operating time
the duration of cervical passage
the intra-operator differences
the differences in pain score between vaginal nullipara and multipara
the acceptability of the procedure again
the preference to undergo the procedure under general anesthesia
adverse events including nausea, vomiting, diarrhoea, fever, abdominal pain and vaginal bleeding
complications such as perforation, bleeding, nausea, vomiting, syncope and heavy pain

Study description

Background summary

When a woman is experiencing abnormal uterine bleeding and/or is suspected of an uterine cavity abnormality the common procedure is a diagnostic or therapeutic hysteroscopy. Other reasons for hysteroscopy comprehend sub fertility, recurrent pregnancy loss and sterilization. Most often hysteroscopy requires extended dilatation of the cervix. There are different procedures to perform a hysteroscopy. In our hospital we perform the vaginoscopic also known as the Bettocchi procedure. Especially in postmenopausal women difficulties can be encountered, since cervical changes decrease elasticity and increase the level of obliteration. Dilating the cervix can be a painful event and tends to be more painful in nulliparous women and in postmenopausal stage. Pain is the reason for failure of hysteroscopy in up to 75% of all cases failed.
Local or general anaesthesia is a time-consuming and not a risk less event which is only to be used when absolutely necessary. Therefore another way of reducing pain is preferred. According to literature cervical ripening and/or dilatation could be facilitated by Misoprostol thus reducing pain.
The few studies performed in postmenopausal patients are conflicting regarding

improvement in cervical dilatation and ease of the procedure with previous use of Misoprostol. More research is needed.

Objective: To evaluate the benefit of Misoprostol prior to hysteroscopy in nulliparous and postmenopausal women regarding the reduction of pain.

Study objective

Misoprostol prior to hysteroscopy in nulliparous and postmenopausal women will reduce pain during the procedure.

Study design

4 moments for measurement: 1. questionnaire before intake of study medication, 2. questionnaire right before the hysteroscopy, 3. use of the continuous pain score meter during the hysteroscopy, 4. questionaire after the hysteroscopy.

Intervention

Treatment exists of Misoprostol (a prostaglandine E1-analogue) compared to placebo. Misoprostol ripens the cervix. Therefore the hypothesis is that Misoprostol decreases the pain experienced during hysteroscopy. This is our primary outcome: pain, measured by a continuous pain score meter and a VAS-score.Intervention- and control-groups are similar, randomisation is double blinded. Patients are either postmenopauzal or premenopauzal nullipara. The duration of the intervention is 24 and 12 hours before the hysteroscopie. The patient takes either Misoprostol or placebo, double blinded.

Contacts

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Eligibility criteria

Inclusion criteria

Indication for diagnostic or therapeutic hysteroscopy

Nulliparity if premenopausal

Postmenopausal state (>1 year after last menstruation)

Adequate command of the Dutch language

Informed consent

Exclusion criteria

Allergy for Misoprostol

Previous cervical surgery or hysteroscopy

Active infection

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-08-2013
Enrollment:	136
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39813
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3948
NTR-old	NTR4113
CCMO	NL38602.029.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39813

Study results

Summary results
N/A