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

Published: 11-04-2013
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To evaluate the benefit of Misoprostol prior to hysteroscopy in nulliparous and postmenopausal women regarding the reduction of pain

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON39813

Source
ToetsingOnline

Brief title
Hysmis Study

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
hysteroscopy, pain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Antonius Onderzoeksfonds

Intervention

Keyword: hysteroscopy, misoprostol, pain, postmenopause

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 number of succesful procedures

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. Nowadays the vaginoscopic hysteroscopy method (also known as the Bettocchi procedure) is increasingly performed. 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.
Regional or general anaesthesia is time-consuming and not without risks and thus should only be used when absolutely necessary. Therefore reducing pain is preferable in order to increase the acceptability of hysteroscopies without anaesthesia. According to the 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.

Study objective

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

Study design

Randomised double blind placebo controlled multi-centred trial

Intervention

Misoprostol 400 mcg 24 and 12 hours pre-operative, or placebo

Study burden and risks

Nil; only minor adverse events such as nausea and diarhoea have been described due to Misoprostol. Furthermore the procedure equals a hysteroscopy outside the trial.

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

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
Active infection

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2013
Enrollment:	136
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cytotec
Generic name:	Misoprostol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2014
Application type:	Amendment
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

ID: 22053
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2011-005160-23-NL
CCMO	NL38602.029.12
OMON	NL-OMON22053