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

Gepubliceerd: 12-08-2013 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22053

Bron
NTR

Verkorte titel
Hysmis

Aandoening

Hysteroscopy/hysteroscopie
Pain/pijn
Misoprostol

Ondersteuning

Primaire sponsor: VUmc
Overige ondersteuning: Sponsor initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain measured by a continuous pain score meter

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Indication for diagnostic or therapeutic hysteroscopy

Nulliparity if premenopausal

Postmenopausal state (>1 year after last menstruation)

Adequate command of the Dutch language

Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Allergy for Misoprostol

Previous cervical surgery or hysteroscopy

Active infection

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	20-08-2013
Aantal proefpersonen:	136
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39813
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A