Nifedipine induced pain relief during hysteroscopy

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The relaxing effect of nifedipine on the uterus will cause pain relief during a hysteroscopy.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20196

Bron
Nationaal Trial Register

Verkorte titel
NIPHY

Aandoening

Pain during hysteroscopic examination or treatment. Pain caused by cervical dilatation. Pain caused by uterine cavity distension.

Ondersteuning

Primaire sponsor: Investigator initiated
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The intensity of pain scored by a visual analogue scale (VAS).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Hysteroscopy is a frequently performed procedure in outpatient setting. One limitation of a hysteroscopy is pain experienced by patients. This pain could lead to failure of the procedure. Currently NSAID’s are prescribed for pain relief during hysteroscopy. Nifedipine, a calcium antagonist, relaxes smooth muscle cells of the uterus and could therefore be a solution to relief the experienced pain during hysteroscopy.

Objective: To compare pain intensity during hysteroscopy when nifedipine, naproxen or placebo is used before the procedure.

Study design: A multicentre single-blinded random naproxen/placebo-controlled pilot trial. Women are asked to score the experienced pain during a hysteroscopy by visual analogue scale (VAS).

Study population: Women of at least 18 years old (not older than 50 years), who are visiting the outpatient gynaecological clinic to undergo a hysteroscopy will be asked to participate.

Intervention: One group receives two 10 mg Nifedipine® capsules 60-30 minutes before starting the procedure and the other groups receive two 250 mg tablets of Naproxen® or two 500 mg placebo tablets 60-30 minutes before the procedure.

Main study parameters/endpoints: The main study parameter will be pain intensity.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is a change of small adverse effects, like palpitations or facial flushing. We expect no serious adverse effects, in which extra visits or contacts are necessary. No additional physical examinations are needed. Women will be asked to fill in a questionnaire before and after the procedure. The potential benefit of the study could lead to pain relief during hysteroscopy and therefore make this procedure less uncomfortable for women. If nifedipine works as pain medication during hysteroscopy it could also have an effect during other gynaecological procedures in which pain is experienced.

Doel van het onderzoek

The relaxing effect of nifedipine on the uterus will cause pain relief during a hysteroscopy.

Onderzoeksopzet

Insertion of the instrument, during the procedure, at the end of the procedure (after removing the scoop), 30 minutes and the day after the hysteroscopy.

Onderzoeksproduct en/of interventie

Nifedipine, naproxen or placebo

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

At least 18 years of age, no medical history of cardiovascular disease, no hypotension; baseline blood pressure greater than or equal to 120/60 mmHg, otherwise healthy women with an average BMI (BMI<30), scheduled for a diagnostic hysteroscopy in outpatient setting

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

50 years of age or older, pregnant or lactating (will be checked by asking the patient), daily use of pain medication (NSAIDs, paracetamol, opioids) or nifedipine or other calcium re-entry blockers, history of complications or adverse effects when using NSAIDs, nifedipine or other calcium re-entry blockers, previously diagnosed hypotension, the use of cardiovascular medication, CYP3A4-inhibitors, rifampicin or magnesium sulfate, previously diagnosed liver or kidney disease

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7750
Ander register	METC UMCU : TBA

Resultaten