A randomized controlled trial comparing paracervical block with a combination of paracervical block and fundal anesthesia during endometrial ablation in the outpatient clinic.

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We perform this randomized trial to test the hypothesis that a combination of paracervical anesthesia and fundal anesthesia is not superior to paracervical anesthesia only.

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

Samenvatting

ID

NL-OMON26448

Bron
NTR

Aandoening

Endometrial ablation
Novasure
Local anesthesia
Paracervical block
Fundal block

Endometriumablatie
Novasure
Lokale anesthesie
Paracervicaal block
Fundusblokkade

Ondersteuning

Primaire sponsor: Máxima Medisch Centrum, Veldhoven
Overige ondersteuning: fonds = verrichter = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the intensity of pain 1 minute into active ablation, using the Visual Analogue Score scale and Numeric Rating scale.

Toelichting onderzoek

Achtergrond van het onderzoek

NovaSure endometrial ablation can be performed in an outpatient setting under local anesthesia or in day-care setting with general or spinal anesthesia.
During the procedure under local anesthesia, women experience high levels of pain. Despite the knowledge that pain is the primary reason for failing to complete gynaecological procedures, we still perform the NovaSure procedure under local anesthesia because the ablation and pain experience takes less than two minutes. The advantages of a procedure under local anesthesia are the reduction of anesthetic risks, shorter hospital stay and recovery time, reduction of operating room utilization and the associated costs.

Two studies showed a reduced pain experience when combining a paracervical block with hysteroscopically guided local anesthesia of the uterine fundus. Since we know this method, we introduced it in our clinic. We noted that women experience less pain, but in our opinion it is not due to the fundal anesthesia. Compared to our old protocol, not only the addition of the anesthetic in the uterine fundus has changed. We use a more extensive paracervical block as well. In our opinion, it is more plausible that the extensive paracervical block causes the decrease in VAS score. Therefore we propose a randomized controlled trial in which this extensive paracervical block is compared to a combination of the same paracervical block and fundal block.

Doel van het onderzoek

We perform this randomized trial to test the hypothesis that a combination of paracervical anesthesia and fundal anesthesia is not superior to paracervical anesthesia only.

Onderzoeksopzet

The women will receive questionnaires to record pain scores and use of pain medication 1, 6 and 24 hours after the procedure. Directly after the treatment and 6 weeks after the procedure the women fill out a questionnaire about adverse effects and satisfaction.

Onderzoeksproduct en/of interventie

In the intervention group, the women receive a intramyometrially injected local anesthetic (ropivacaine 2mg/ml) in the uterine fundus after the placement of an extensive paracervical block. In the control group, women receive the same paracervical block and in the uterine fundus, they get injections with natriumchloride 0.9% instead of ropivacaine.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Premenopausal women (≥18 years), ASA classification 1-2, with menorrhagia, who are planned for a NovaSure endometrial ablation under local anesthesia.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women younger than 18 years

Women who do not understand Dutch

Women who might want to get pregnant in the future

Women with low body weight (under 45 kilograms)

Allergic/intolerance to amides (type of local anesthetic)

Women suffering from methemoglobinemia

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2015
Aantal proefpersonen:	96
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL5499
NTR-old	NTR5634
Ander register	METC Maxima Medisch Centrum : 15.110.

Resultaten