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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To compare a combination of paracervical anesthesia and fundal anesthesia with paracervical anesthesia only during endometrial ablation.

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

Summary

ID

NL-OMON43705

Source
ToetsingOnline

Brief title
Local fundal anesthesia during endometrial ablation (RCT)

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
pain during active endometrial ablation

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Stichting Top Onderzoek Gynaecologie en Obstetrie

Intervention

Keyword: endometrial ablation, fundal block, local anesthesia, paracervical block

Outcome measures

Primary outcome

Pain score during active ablation, using the Faces Pain Scale and Verbal Rating

Scale.

Secondary outcome

- Pain scores and pulse rate during hysteroscopy, cervical dilatation and 1, 6

and 24 hours after the procedure. 'Overall' pain score directly after the

procedure.

- Impression of the experienced pain, rated by the gynecologist (by the numeric

rating scale, 0-10)

- Use of pain medication after the procedure

- Adverse effects and complications

- Satisfaction about the treatment and the anesthesia

Study description

Background summary

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. The primary endpoint is the perception of pain during the Novasure® procedure.
When there is no difference in VAS score between both groups, we only need to change our method of (para)cervical anesthesia and do not need the special hysteroscopy instruments (syringes) for performing the fundal anesthesia. Besides, this would reduce the risk of toxicity and perforation.

Study objective

To compare a combination of paracervical anesthesia and fundal anesthesia with paracervical anesthesia only during endometrial ablation.

Study design

A double-blind randomized controlled trial

Intervention

All patients will be anesthetized with the same paracervical block. Women in the intervention group wil receive hysteroscopically guided, intramyometrially injected local anesthesia in the uterine fundus (4x1 ml of ropivacaine 2mg/ml). Women in the controlgroup will receive the same injections with natriumchloride 0.9% instead of ropivacaine.

Study burden and risks

In case of better pain reduction in the intervention group (combination of paracervical and fundal anesthesia), women in the control group experience higher levels of pain (compared to the standard care). We perform a non-inferiority study, so we expect the same levels of pain in both groups. Until now, there are only two studies which investigated fundal anesthesia.

Both studies demonstrated that combining a (para)cervical and fundal block significantly reduces the pain perception. Besides, no major complications or adverse reactions were described in both studies. In one study, only three women (10%) experienced a vasovagal response with spontaneous recovery. In the other study, 12% of the women reported a slight dizziness or light-headedness (with stable vital parameters) after injection of the fundal block. In our pilot study (N=10) no adverse effects or complications were reported.

The women fill out a couple of questionnaires (directly before and after the procedure, and 1, 6 and 24 hours after the procedure), which will take 15 minutes.
If we conclude that fundal anesthesia is not neccessary, this has safety and economic benefits in the future.

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

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

Exclusion criteria

- 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

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):	07-12-2015
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	25-11-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	11-08-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL55215.015.15