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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26448

Source
NTR

Health condition

Endometrial ablation
Novasure
Local anesthesia
Paracervical block
Fundal block

Endometriumablatie
Novasure
Lokale anesthesie
Paracervicaal block
Fundusblokkade

Sponsors and support

Primary sponsor: Máxima Medisch Centrum, Veldhoven
Source(s) of monetary or material Support: fonds = verrichter = sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcomes are the intensity of pain during hysteroscopy, cervical dilatation and 1, 6 and 24 hours after the procedure. Furthermore, postoperative use of pain medication, complications, adverse effects and satisfaction will be compared.
Impression of pain during the treatment noted by the gynecologist and nurse.

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Máxima Medisch Centrum

Imke Reinders
De Run 4600

Veldhoven 5500 MB
The Netherlands
phonenumber: +31621946368
Scientific
Máxima Medisch Centrum

Imke Reinders
De Run 4600

Veldhoven 5500 MB
The Netherlands
phonenumber: +31621946368

Eligibility criteria

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2015
Enrollment:	96
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type: Not applicable

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
NTR-new	NL5499
NTR-old	NTR5634
Other	METC Maxima Medisch Centrum : 15.110.

Study results