Prevalence of intrauterine adhesions after NovaSure ablation with application of Hyaluronic acid

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23959

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Intraurineadhesions after endometrial ablation

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

We will investigate the prevalence and describe the severity of IUAs (using a valid scoring system, the American Fertility Society (AFS) classification system) following NovaSure treatment for HMB with NCH gel compared to a NovaSure treatment without the NCH gel. In

order to prepare for a future hypothesis testing randomized trial.

Secondary outcome

We will also investigate the complications (like uterus perforation and infection) that can occur during administration of the NCH gel in the uterus. Also, we will investigate dysmenorrhoea/ abdominal pain, PBAC score and menstrual bleeding pattern and patient's satisfaction between the group of patients following NovaSure treatment with NCH and without the NCH gel.

Study description

Background summary

Rationale: Heavy menstrual bleeding (HMB) is a common problem in women of reproductive age. An alternative to hysterectomy in the treatment of HMB is endometrial ablation. Endometrial ablation will destroy the basal layer of the endometrium. Necrosis, degeneration and fibrosis occurs, to alleviate menstrual symptoms. However, destruction of the endometrium and the subsequent inflammatory reaction may result in intrauterine adhesions (IUAs). Given the variability in presentation, the prevalence of IUAs is difficult to estimate precisely. [14]
Postablation IUAs were found up to 52.8%, which may become progressively more sever over time. IUAs can lead to partial or complete closure of the uterine cavity and may cause hematometra, severe cramping pelvic pain and difficulties in accessing the uterine cavity during hysteroscopy. This may result in a possible potential delay in the diagnosis of endometrial carcinoma. [8]
A variety of anti-adhesive gels have been used to protect the endometrium and to prevent IUAs after endometrial ablation. New crosslinked hyaluronan (NCH) gel creates an anti-adhesion barrier to keep the healing tissue separated during the critical repair phase. [7]
Different studies have shown a significantly effect of NCH gel in reducing adhesion formation after laparoscopic and hysteroscopic surgery. However, whether this adjuvant therapy with an anti-adhesive gel is effective to prevent the development of IUAs after a NovaSure endometrial ablation remains controversial.
Objective: To evaluate the efficacy of intrauterine application of MateRegen®Gel, a crosslinked hyaluronan gel, in reducing the formation of postoperative IUAs after NovaSure ablation.
Study design: Pilot study of 20 patients.
Study population: Woman with HMB and who are scheduled for NovaSure endometrial ablation are eligible if they agree undergoing a hysteroscopy 6 months after endometrial ablation to assess the uterine cavity.
Intervention: Directly after the NovaSure ablation 10ml MateRegen is inserted in the uterine cavity.
Main study parameters/endpoints: The main study parameters are the number of women with IUAs and severity of the IUAs, objectified during hysteroscopy 6 months after the

intervention. Secondary endpoints are complications, pelvic/abdominal pain, patient satisfaction and menstruation bleeding pattern at time of follow-up.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
One extra visit to the hospital is required. A diagnostic hysteroscopy is performed at 6 months. We ask the patients to fill in two short questionnaires at 6 weeks, 3 and 6 months after the NovaSure to assess vaginal bleeding and pelvic pain.
Installation of MateRegen has a potential risk of uterine perforation by the stump inserter, however this has no clinical implications.

Study objective

There are minor intrauterine adhesions after instillation of MateRegen at time of a Novasure ablation in comparison with a Novasure ablation without MateRegen.

Study design

- time of inclusion
- 6 weeks
- 3 months
- 6 months

Intervention

Intrauterine instillation of MateRegen gel after NovaSure treatment.

Contacts

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Eligibility criteria

Inclusion criteria

• Women suffering symptoms from HMB, scheduled for a NovaSure endometrial ablation
• Women in pre-menopausal age

Exclusion criteria

• Women younger than 34
• Women with a desire to preserve fertility
• Women with intracavitary pathology or big intramural myoma seen by transvaginal ultrasound.
• Women with a history of a previous endometrial ablation or curettage
• Women with cervix pathology

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-05-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48385
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7714
CCMO	NL69032.015.19
OMON	NL-OMON48385

Study results