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

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To evaluate the efficacy of intrauterine application of MateRegen®Gel, a crosslinked hyaluronan gel, in reducing the formation of postoperative intrauterine adhesions after NovaSure ablation.

Ethical review	Not approved
Status	Will not start
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON48385

Source
ToetsingOnline

Brief title
Intrauterine adhesions after NovaSure ablation

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
intrauterine adhesions

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie & Obstetrie
Source(s) of monetary or material Support: geen financiering

Intervention

Keyword: Endometrial ablation, Hyaluronic acid, Intrauterine adhesions, MateRegen, Novasure

Outcome measures

Primary outcome

o the number of women with intrauterine adhesions, defined fibrous string at

opposing wall of the uterus and/or cervix leading to partial or complete

obliteration of the cavity

o the severity of the intrauterine adhesions according to the AFS

classification system

Secondary outcome

o Complications: uterus perforation and infection

o Pain during and beyond menstruation according to the numeric rating scale

(NRS)

o Patient satisfaction according to the Likertscale

o PBAC score and Menstruation bleeding pattern

Study description

Background summary

Heavy menstrual bleeding (HMB) is a common problem in women of reproductive age and is one of the most important reasons for consulting a gynaecologist. HMB is defined as menstrual blood loss exceeding 80mL from normal secretory endometrium. The incidence varies between 9% and 14%.[1,9,10,11,13] This disorder may lead to physical consequences as iron deficiency anaemia but is also associated with effect on the medical, socioeconomic, and psychologic well-being of women. [3,5,11] Of all hysterectomies, approximately 30-40% are performed for treatment of severe dysfunctional bleeding. [11,12] Despite the fact that hysterectomy is a definitive solution for the treatment of

menorrhagia, many women opt a less invasive treatment.
An alternative to hysterectomy in woman with HMB is endometrial ablation. Endometrial ablation is an established treatment of dysfunctional uterine bleeding. Many endometrial ablation techniques have been evaluated and currently have been established as a common daily practise. The NovaSure endometrial ablation device is one of the second-generation devices that use bipolar radiofrequency, impedance-controlled endometrial ablation to evaporate endometrial tissue. Endometrial ablation has proved to be safe and effective in management of menorrhagia due to benign causes.

Intrauterine adhesions (IUA), represents a gynaecologic disease that leads to partial or complete closure of the uterine cavity. [14] Intrauterine adhesions are fibrous intrauterine bands on opposing walls of the uterus. The primary factors that may trigger intrauterine adhesion formation include curettage after abortion or postpartum, infections, prolonged retention of an intrauterine device, operative hysteroscopy or other operations that can injure the endometrium. [2,14] Approximately 90% of severe intrauterine adhesions are related to curettage performed because of complications of pregnancy. However, adhesions can develop in the non-gravid uterus after endometrial injury from procedures as operative hysteroscopy.[2] As any trauma caused by injury of the basal lamina of the endometrium can lead to endometrial wall adhesions, a NovaSure treatment may be accompanied by intrauterine adhesions. Endometrial ablation will destroy the basal layer of the endometrium down to the superficial myometrial layer. Necrosis, degeneration, and fibrosis occur, resulting in alleviation of menstrual symptoms. [8] The endometrium undergoes necrosis with variable degrees of acute inflammation, followed by a phase of chronic repair and regeneration with granulomatous reaction. This process results in most cases in striking endometrial scarring and fibrosis. [6,8] However, destruction of the endometrium and the inflammatory reaction may result in formation of intrauterine adhesions. [6,8]
Furthermore, the myometrium that is exposed after ablation and the close proximity of the anterior and posterior uterine walls raise concerns about postoperative formation of intrauterine adhesions. Given the variability in presentation, the prevalence of intrauterine adhesions is difficult to precisely estimate. [14] Available studies suggest that the uterine cavity had variable degrees of fibrosis after endometrial ablation.[6,8] In a previous observational study by Leung et al.[6] postablation intrauterine adhesions were found in 36.4% after thermal balloon endometrial ablation. Adhesions mostly involved in the fundal region, but 9% of patients had complete obliteration of the cavity. The incidence of fibrotic cavity was 18%. [6] Also, Luo et al. described various types of intrauterine adhesions in 52.8% six months after microwave endometrial ablation. They concluded that the degree of intrauterine adhesions may become progressively more severe over time and post-operative intrauterine adhesions may be a major long-term complication of endometrial ablation. [4,6] However, the incidence of intrauterine adhesions after NovaSure endometrium ablation technique has not been fully documented.
Intrauterine adhesions are clinically important. intrauterine adhesions can

lead to partial or complete closure of the uterine cavity. Intrauterine adhesions that either partially or completely obstruct the isthmus or the internal uterine ostium may cause hematometra, severe cramping pelvic pain and difficulties in accessing the uterine cavity during office hysteroscopy. [2] A potential delay in the diagnosis of endometrial carcinoma is therefore possible. [6,8]
A variety of antiadhesive gels, which are found to be convenient and safe, have been used to protect the endometrium and prevent or decrease formation of intrauterine adhesions. According to Yan et. al. [14] auto-cross-linked hyaluronic acid (ACP) gel exert a substantial preventive effect against intrauterine adhesions.[14] In a further randomized controlled trial, Guida et al. [4] found ACP to be effective in reducing the number and severity of de-novo- formation of intrauterine adhesions after hysteroscopic surgery. [4]
Recently, a new crosslinked hyaluronan (NCH) gel has been developed to serve as an absorbable adhesion barrier, which has a much higher viscosity and is gradually absorbed within 1 to 2 weeks in vivo. [7] The NCH gel creates an antiadhesion barrier to keep the healing tissue separated during the critical repair phase. [7] A randomised controlled study by Liu et al. [7], demonstrates that NCH gel is safe and significantly reduces adnexal adhesion formation and global adhesion formation throughout the abdominopelvic cavity after gynaecologic laparoscopic surgery.[7]
However, whether this adjuvant therapy with an antiadhesive gel is effective to prevent to development of intrauterine adhesions after a NovaSure endometrial ablation remains controversial.
In this pilot study, we will assess the efficacy of NCH gel in preventing and decreasing the formation of intrauterine adhesions after endometrial ablation.

Study objective

To evaluate the efficacy of intrauterine application of MateRegen®Gel, a crosslinked hyaluronan gel, in reducing the formation of postoperative intrauterine adhesions after NovaSure ablation.

Study design

Pilot study of 20 patients.

Intervention

Instillation of MateRegen gel after Novasure ablation.

Study burden and risks

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 to assess bleeding and pain.

Installation of MateRegen has a potential risk of uterine perforation by the stump inserter, however this has no clinical implications.

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

Women suffering symptoms from heavy menstrual bleeding, scheduled for a NovaSure endometrial ablation

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 cervix pathology

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	MateRegen
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	13-06-2019
Application type:	First submission
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

ID: 23959
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69032.015.19
OMON	NL-OMON23959