

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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23959

Bron

NTR

Verkorte titel

TBA

Aandoening

Intraurineadhesions after endometrial ablation

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 (IUA's). Given the variability in presentation, the prevalence of IUA's is difficult to estimate precisely. [14]

Postablation IUA's were found up to 52.8%, which may become progressively more severe over time. IUA's 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 IUA's 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 IUA's 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 IUA's 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 IUA's and severity of the IUA's, 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Intrauterine instillation of MateRegen gel after NovaSure treatment.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Controle: Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2019
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 06-05-2019

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48385

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten