Evaluation of adhesions formation using conventional third generation endometrial ablation with and without postoperative application of an intrauterine adhesion barrier film

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Evaluate the formation of adhesions after third-generation endometrial ablation, with and without the intrauterine adhesion barrier

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic and nontherapeutic effects (excl toxicity)
Study type	Interventional

Summary

ID

NL-OMON51498

Source
ToetsingOnline

Brief title
CLEAN

Condition

- Therapeutic and nontherapeutic effects (excl toxicity)

Synonym
Intra-uterine adhesions

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Stichting Vrouw en Onderzoek

Intervention

Keyword: Barrier film (Womed Leaf), Endometrial ablation (NovaSure), Intrauterine adhesion (IUA)

Outcome measures

Primary outcome

Primary efficacy endpoint:

AFS score focused on the intrauterine adhesion formation following Novasure

(i.e. considering only extent of cavity involved and type of adhesions after)

at 4-6 weeks

Primary safety endpoints:

1. Assessment of cavity findings at 4-6 weeks

a. Ability to perform a biopsy anywhere within the uterine cavity

b. Ability to adequately visualise the endometrium to evaluate for pathologic

change

c. Qualitative description of the endometrial cavity (i.e. presence of viable

endometrium vs cicatricial/fibrotic tissue*)

2. Number of Serious Adverse Events and Serious Device-related Adverse Events

at 3 months

Secondary outcome

1. Each component of AFS score at second look hysteroscopy: extent of IUA, type

of IUA

2. Binary rate of intrauterine adhesions on hysteroscopy

3. Change in menstrual bleeding at 3 months using Pictorial Blood Loss

Assessment Chart

4. Level of dysmenorrhea before and after 3 months (painful cramping associated

with menstruation)

5. Level of patient satisfaction on ablation procedure on a scale from 0 to 5

from the worst to the best health care possible.

6. Patients complaints (discharge, dyspareunia)

7. Is it possible to perform a second ablation procedure in case needed?

8. Histopathology assessment of hysterectomy piece (in the case a

hysterectomy is performed few years after endometrial ablation)

9. Histopathology assessment of endometrial biopsy taken at second look

hysteroscopy

Study description

Background summary

The application of endometrial ablation (EA) has significantly increased in the past 10 years. It is an effective treatment for heavy menstrual bleeding with functional aetiology, in the absence of other uterine pathology and child wish. However, the risk of post-ablative intracavitary scarring after EA is significant and can lead to long term complications, and the possible delay in diagnosing of endometrial cancer , .
Although poorly documented, ablation using radiofrequency such as endometrial ablation with Novasure has been associated with a high rate of post- ablation intrauterine adhesions, limiting the ability to adequately evaluate the endometrium by biopsy or hysteroscopy to address subsequent abnormal uterine bleeding (AUB) .
In this clinical trial, we aim to perform a short term evaluation of the

uterine cavity and document the formation of adhesions with or without a prevention barrier. Womed Leaf* is an intrauterine adhesion barrier film specifically developed to prevent the formation or recurrence of intrauterine adhesions after transcervical procedures, and it will be selected as the test barrier in this study.

Results from this study, representing a relatively small cohort of patients, will allow setting the hypothesis for a larger trial on long term EA outcomes and complications depending on early management of adhesions.

Study objective

Evaluate the formation of adhesions after third-generation endometrial ablation, with and without the intrauterine adhesion barrier

Study design

Prospective, multicenter, randomised, controlled, two-arm pilot clinical trial.

Intervention

Womed Leaf is inserted immediately after completion of the endometrial ablation

Name: Womed Leaf*
Device group: Intrauterine adhesion barrier
Device status: CE mark
Description:
Womed Leaf* is a sterile, degradable film of poly(D,L-lactide) (PLA) and poly(ethylene oxide) (PEO). PEO is a biocompatible polymer with anti-adhesion and swelling properties. It is polymerized with hydrophobic PLA to form a degradable film
Womed Leaf* is inserted in the uterine cavity by a gynaecologist surgeon with a 5 mm diameter flexible inserter. Once released, the film unfolds and grows into the uterine cavity to create a mechanical barrier and keep the uterine walls separated for approximately one week. It is then degraded and discharged naturally through the cervix.

Study burden and risks

No device-related adverse events were reported in the safety clinical study PREG1 (NCT04381728), demonstrating that the device insertion is safe and the uterine film is well tolerated by the patients.

Any known risks for participation in this study will be minimised through centre selection and training as well as in the conduct and management of the study, including a careful selection of patients, compliance with the protocol

and investigational device instructions for use.

The risk of performing additional second look hysteroscopy at 4-6 weeks (study-specific) is comparable to an outpatient-based hysteroscopic diagnostic procedure*s risks and complications. It will be done without anesthesia, which is standard practice in the Netherlands.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1.Patient with refractory heavy menstrual bleeding scheduled for endometrial ablation with NovaSure system
2.Women 30 years old or older;
3.Subjects who are willing to provide a written informed consent as approved by the applicable Ethics Committee / IRB prior to participating in this clinical

investigation.
4.Subjects who can comply with the study follow-up and other study requirements.

Exclusion criteria

1. Cavity length <4 or >8
2. Perforation during the ablation procedure
3. Previous adhesiolysis procedure or diagnosis of Asherman's disease.
4. An abnormal uterine cavity at the time of ablation according to ESHRE classification I to V, such as unicornis, bicornis, septate, duplex
5. Medical history of cervical or endometrial cancer
6. Active pelvic infection or medical history of pelvic peritonitis
7. An intrauterine device in situ
8. Known contraindication or hypersensitivity to PEO or PLA
9. Current participation in another clinical investigation that has not yet received the primary endpoint
10. Any other condition that makes participation in the study contrary to the patient*s best interests.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Womed Leaf
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-10-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT05414760
CCMO	NL81229.100.22