PREvention of intrauterine adhesion after hysteroscopic surgery with novel deGradable film

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The objective of the present study is to evaluate the safety of Womed Leaf after hysteroscopic myomectomy and its potential efficacy in preventing IUA at second look hysteroscopy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female benign
Study type	Interventional

Summary

ID

NL-OMON49341

Source
ToetsingOnline

Brief title
PREG1

Condition

- Reproductive neoplasms female benign
- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Adhesions after hysteroscopy

Research involving
Human

Sponsors and support

Primary sponsor: WOMED

Source(s) of monetary or material Support: Womed (sponsor van de studie)

Intervention

Keyword: Adhesion, Hysteroscopy, Myomectomy

Outcome measures

Primary outcome

The primary endpoints for safety and efficacy:

Safety endpoint: number and type of device-related adverse events (AE) up to 30 days:

* Per-operative AEs during device use (cervical trauma, uterine perforation*)

* Polymer film tolerance defined as fever, pain or bleeding between 48 hours post procedure and 30 days

An Interim Analysis of the safety endpoint will be conducted on the first 10 subjects at 30 day follow-up.

Efficacy endpoint: freedom from intrauterine adhesion at second look hysteroscopy between 4 and 8 weeks, and evaluation of severity according to American Fertility Society (AFS) and European Society of Gynecological Endoscopy classifications systems of adhesions.

Secondary outcome

Key secondary endpoints:

1. Number, type and severity of adverse events (AE) at 30 days

2. Performance: device technical success, defined as success of the following 2

steps :

a. Menstrual bleeding according to Higham score

4. Presence of Womed Leaf residuals in the uterus at hysteroscopic control

after 4-8 weeks

Study description

Background summary

IUAs are the major long-term complication of operative hysteroscopy. Their prevalence following myomectomy is high (31.3%-45.5%, , and they are frequently associated with pelvic pain . According to the Cochrane review performed by Bosteels et al, the effectiveness of the anti-adhesion techniques evaluated in the literature in decreasing intrauterine adhesions following hysteroscopy in subfertile women remains uncertain . The latest study by Hooker et al demonstrates that barrier gel can reduce IUAs formation. However IUAs still develop and there is room for improvement in adhesion formation prevention.
The prevention tools available today do not sufficiently meet the specifications required for the prevention of IUAs which are: 1) ergonomic device, specifically designed for intrauterine use and adapted to the cervical passage and 2) anti-adhesion barrier that keep the wound tissue apart during the repair phase for optimal efficiency. *Results can be used to prevent adhesions and to preserve the ability to become pregnant

Study objective

The objective of the present study is to evaluate the safety of Womed Leaf after hysteroscopic myomectomy and its potential efficacy in preventing IUA at second look hysteroscopy.

Study design

This is a prospective, multi-center, single arm clinical study. Second look hysteroscopy at 4-8 months will enable to assess device efficacy.

Intervention

Womed Leaf* is inserted in the uterine cavity by a gynecologist surgeon as a

film folded into a 5 mm diameter flexible inserter. Once released, the film will unfold and swell into the uterine cavity to keep uterus walls separated during approximately 5 days. It is degraded and discharged naturally through the cervix and vagina in less than 30 days

Study burden and risks

There are three types of risk:
1. Risk associated with inserting the film through the applicator. However, this type of risk is small because the device is specifically designed for introduction into the uterus in a non-traumatic manner. These risks are:

* Damage to the cervix if it closes spontaneously after hysteroscopy, thus causing some fricture when applying the film. These small lesions heal spontaneously.
* Very rarely, uterine perforation may occur. There is then a risk that surrounding organs will be damaged. A viewing operation through the abdominal wall may then be necessary to assess the potential damage and remove the film if it is in the abdominal cavity.

2.Tolerance for the film itself. The film is made up of various elements (polylactic acid and polyethylene oxide). These elements are already being used in a number of other clinical applications: suture, bone implants, cosmetics, medicines. The tolerance of the film has been thoroughly studied and the results show that the film does not cause a reaction when it comes into contact with tissues.
However, it is possible that an allergic reaction or infection may occur that leads to itching, discomfort or fever, pain or bleeding. This may then be due to surgical hysteroscopy or to Womed Leaf. If the film was not tolerated by the uterus, it is possible that the film will be rejected by uterine contraction.
Animal studies have shown that the film will be degraded and excreted within 28 days, ro be confirmed by the hysteroscopy at 4-8 weeks. If part of the film is still present, this should have no consequences due to the excellent tolerance of the substance.

3.Risks associated with operative hysteroscopy itself. These risks are therefore related to the surgical procedure and not to Womed Leaf.

The burden on the patient is low, only insertion through an applicator after the operative hysteroscopy. further only follow-up after 30 days and a follow-up viewing after 4-8 weeks. The risks are reduced as much as possible through targeted site selection and training, and proctoring. The Instructions for use have been developed as well as possible.
Any known risks for participation in this study have been minimized during the development process of the device and will be minimized through center selection and training, proctoring 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

Contacts

Public
WOMED

Avenue Charles Flahault 15
Montpellier 34090
FR
Scientific
WOMED

Avenue Charles Flahault 15
Montpellier 34090
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Women * 40 years AND no childbearing wish until the second look hysteroscopy, OR history of permanent sterilization;
* Subject scheduled for myomectomy for one or more myoma(s) where one myoma is at least 10mm in size (*10mm) as estimated by pre-operative ultrasound measurement of the largest diameter
* Hysterometry prior to device insertion * 6cm and * 9cm.
* Subjects who are willing to provide a written informed consent as approved by the applicable Ethics Committee prior to participating in this clinical investigation.

* Subjects who can comply with the study follow-up or other study requirements

Exclusion criteria

* Current pregnancy
* Abnormal uterine cavity
* Known or suspected endometrial hyperplasia
* Medical history of cervical or endometrial cancer

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2020
Enrollment:	12
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	17-10-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-01-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-10-2020
Application type:	Amendment
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
CCMO	NL70942.100.19