A Post-Market Clinical Follow-up Study to Investigate the Usability of the CollaGUARD Adhesion Barrier following Hysteroscopic Adhesiolysis

Published: 08-10-2014
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41131

Source
ToetsingOnline

Brief title
INN-CG-001

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
adherence of internal walls of the uterus, intrauterine adhesions (IUA)

Research involving
Human

Sponsors and support

Primary sponsor: Innocoll Technologies

Source(s) of monetary or material Support: Innocoll Technologies

Intervention

Keyword: - Adhesion Barrier, - Hysteroscopic surgery, - Intra-Uterine Adhesions

Outcome measures

Primary outcome

The primary endpoint of this clinical investigation is to determine the

usability of the use of CollaGUARD in hysteroscopic adhesiolysis.

Safety shall be assessed by means of recording serious adverse events. The

safety endpoint of this trial is freedom from unexpected serious device related

adverse events during the complete study period.

Secondary outcome

The secondary endpoints of this clinical investigation are:

- The number of de novo adhesions and adhesion reformations

- Change in severity of the adhesions based on the ESGE and mAFS IUA

classification scale at all follow-up visits

- Product positioning and degradation level at each follow-up visit

Study description

Background summary

The development of intrauterine adhesions (IUA) following gynecological surgery is a major
complication which may cause a range of severe clinical symptoms in women. IUA*s can result in menstrual abnormalities, dysmenorrhea and infertility. IUA*s are thought to develop as a result of trauma to the uterine cavity, related to, for instance, curettage, infections and surgical

hysteroscopy. Post-operative adhesions are classified as *de novo *when they develop at sites that did not have adhesions before, and are considered *reformed* when they develop at sites where previous adhesiolysis has been performed. Corrective surgery is often needed to resolve adhesion-related complications, and prevention of adhesions is therefore considered important.

The insertion of an intrauterine device has been shown by many studies as an effective method of preventing adhesion reformation. Post-operative use of an IUD keeps the surfaces of the uterus separated during the initial healing phase, and reduces the chance that the surfaces will adhere. IUDs include, among others, Foley-balloons and barrier gels. The Foley balloon has been shown to prevent reformation of IUA*s. However inserting a Foley balloon catheter carries a risk of infection spread from the vagina and the inflated balloon may cause a decreased blood flow to the uterine walls, slowing regeneration. Additionally, the method can cause discomfort the patient. When using a barrier gel, the application of it prevents adhesions by forming a protective coating on the uterine wall. A disadvantage of gel formulations is the fact that in case of bleeding they may be washed out of the uterine cavity, losing its efficacy. Other adhesion barriers have been developed, including barriers consisting of collagen. Collagen is a fully biodegradable and bioactive material and has been shown to act as an effective adhesion barrier in isolation and in combination with polymers. The CollaGUARD adhesion barrier is such a collagen adhesion barrier.

CollaGUARD adhesion barrier is a transparent bioresorbable film of 100% type I purified equine collagen. CollaGUARD is approved in Europe for the prevention of postoperative adhesions in patients undergoing abdomino-pelvic laparotomy or laparoscopy and has a CE certification since October 2011. CollaGUARD can be implanted at the time of surgery and serves as a temporary barrier to separate adhesiogenic surfaces throughout the normal tissue repair process. can be easily rolled for insertion through a trocar when implanted laparoscopically. CollaGUARD is fully resorbed by the human body by means of enzymatic degradation by collagenases. The resorption time is about 4 weeks. A pre-clinical study using CollaGUARD adhesion barrier in a rat-abrasion model showed that CollaGUARD increased the probability of remaining adhesion free by more than six-fold ($P < 0.001$) and significantly reduced the extent and severity of adhesions ($P < 0.001$). Safety of the CollaGUARD adhesion barrier was evaluated in this study by histopathological analysis of acute and/or chronic inflammation reaction. Results showed good local tolerance of the CollaGUARD adhesion barrier. Based upon this data and extensive clinical experience with collagen-based products in other fields of application, CollaGUARD was determined to have a positive risk-benefit ratio. Furthermore, there have been no spontaneous reports of any adverse device effects since launch. CollaGUARD is expected to reduce adhesion reformation and formation of de novo adhesions.

Study objective

This study is designed to determine the usability of the CollaGUARD adhesion barrier in gynecological surgery. The aim is to collect qualitative and quantitative data in a small number of subjects (pilot study) to gain information on the usability and implantation procedures of the CollaGUARD adhesion device in hysteroscopic surgery. Results from this study can be used to design statistically powered clinical trials for the investigation of efficacy parameters.

Study design

This is a multicenter post-marketing pilot study. In total, 10 patients will be implanted at two investigational sites in the Netherlands. Patients deemed eligible after screening, and who gave written consent for participation in the trial, will be treated with the CollaGUARD adhesion barrier according to the Instructions for Use during the hysterscopic adhesiolysis. Directly after surgery, an ultrasound will be done to assess the position of the device. The Investigator will complete a series of questions regarding the usability of the device. Also, he will classify the adhesion severity before and after the surgery (using ESGE and mAFS scales). Subjects are prescribed medication to induce withdrawal bleeding, and are followed up as following:

1 week post-op: safety phone call. If deemed necessary by the investigator, a control visit in the hospital can be scheduled.

2 week post-op: control visit. An additional ultrasound will be done to assess the location and degradation of the device.

3 week post-op: safety phone call. If deemed necessary by the investigator, a control visit in the hospital can be scheduled.

4 week post-op: control visit. An additional ultrasound will be done to assess the location and degradation of the device.

9 week post-op: control visit. A follow-up hysteroscopy will be performed to classify adhesion reformation and de novo formation. This hysteroscopy is according standard practice.

The clinical investigation is expected to take approximately 8 months: an estimated 3-5 months recruitment period and 9 weeks of follow-up for each patient.

Study burden and risks

Possible risks of participating in this trial are associated with the

hysteroscopic procedure and with non-active implants that are left in situ.
These anticipated risks are the following and are not considered unique for the CollaGUARD device:
- Blood loss
- Perforation of the uterus wall
- Allergic reaction
- Infection of the uterus
- Formation of granulomas

Potential risks associated with the CollaGUARD device are:
- Allergic reactions due to hypersensitivity to collagen
- Blood and/or fluid accumulation in uterus (due to blockage of flow by the device)
- Infection

Besides these anticipated risks, patients can experience extra burden by the two additional visits and ultrasounds at the 2 and 4 week FU visits, which are not standard of care. Potential benefits are expected for the patient by means of reduced de novo and reformation adhesions, and consequently reduced symptoms. Because the additional burden and risks compared to the standard care are minimal, the potential benefits for the patients and the advantage for future research outweigh the potential risks posed to the participating subjects.

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

- Be a female >=18 and <= 45 years of age
- Diagnosed with intrauterine adhesions and found eligible for hysteroscopic adhesiolysis
- Willing to use additional contraception until the study is completed
- Understand and be willing to follow all aspects of the study protocol and is able to provide written Informed Consent prior to any study-related procedures being performed

Exclusion criteria

- Be pregnant or having a suspected molar pregnancy, lactating, or planning to become pregnant at any time during the study
- Be a female of childbearing potential not using a reliable means of contraception
- Has suffered or currently suffers from a gynaecological malignancy
- Has a current genital infection
- Has a known or suspected hypersensitivity to collagen
- Has a known or suspected increased risk of infections (due to e.g. (auto)immune diseases or taking medications influencing infection risk)
- Has undergone a previous hysteroscopic surgery (such as removal of fibroids)
- Has a condition or be in a situation that, in the Investigator*s opinion, may put the subject at significant risk, may confound the study results, or may interfere significantly with the subject*s participation in the study
- No adhesion formation present in the uterus
- Severe adhesion formation which cannot be removed in one procedure
- Has a condition or be in a situation which could only be determined during the hysteroscopic procedure that, in the Investigator*s opinion, may put the subject at significant risk, may confound the study results, or may interfere significantly with the subject*s participation in the study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2014
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	CollaGUARD adhesion barrier
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-10-2014
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL49783.072.14