Evaluation Of Uterine Patency following Sonography-guided Transcervical Ablation of Fibroids

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The objective of the OPEN Study is to document the presence or absence of intrauterine adhesions after treatment with the Sonata System when used in women with submucous and/or transmural fibroids in accordance with product labeling.An evaluation...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Observational invasive

Summary

ID

NL-OMON45454

Source
ToetsingOnline

Brief title
The OPEN study

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
formation of adhesion, Synechiae

Research involving
Human

Sponsors and support

Primary sponsor: Gynesonics, Inc
Source(s) of monetary or material Support: Gynesonics inc

Intervention

Keyword: hysteroscopy, intrauterine synechiae, uterine fibroids

Outcome measures

Primary outcome

Incidence of the formation of new intrauterine synechiae at six weeks will be assessed.

Identified adhesions will be classified per the European Society of Hysteroscopy (ESH) scoring system.

Secondary outcome

In addition to the documentation of the presence of adhesions after sonata treatment, the effect of the sonata treatment on recovery after treatment (treatment recovery questionnaire), on the subjects quality of live (E-Q-5D questionnaire) and subject satisfaction with treatment (Subject Satisfaction and Overall Treatment Effect questionnaire) will be assessed. Furthermore adverse events and surgical re-interventions will be documented

Study description

Background summary

Uterine fibroids or myomata are the most common benign tumors in women. The prevalence of fibroids is approximately 20-25% in adult women, and the incidence increases with premenopausal age. The lifetime risk of developing fibroids is as high as 70% in white women and greater than 80% in black women. Most fibroids are asymptomatic. However, depending on the size and location of the tumors, fibroids can be symptomatic and may involve one or more of the following: heavy menstrual bleeding (HMB), dyspareunia, dysmenorrhea, anemia, pelvic/abdominal pressure, urinary retention, constipation, subfertility, pregnancy loss and preterm labor. Because they are prevalent and often symptomatic, fibroids impact the quality of life of millions of women and are

associated with an increased utilization of health care resources involving treatments that are often invasive and expensive.
There are several treatment options for uterine fibroids such as the Sonata System, which combines intrauterine ultrasound (IUUS) with radiofrequency (RF) ablation. Surgical options for treatment of myomata include hysterectomy and myomectomy, each of which can be performed via a number of approaches, such as laparotomy, laparoscopy, and hysteroscopy.
One risk associated with some treatment options is adhesiogenesis. Obliteration of the endometrial cavity by adhesions can result in amenorrhea (Asherman syndrome), but lesser degrees of synechiae can impair fecundity and be associated with abnormal uterine bleeding and secondary dysmenorrhea. The pathophysiology involves mechanical disruption of the basalis layer of the endometrium (as after vigorous curettage), preventing endometrial regeneration; local infection may also predispose to intrauterine adhesiogenesis. With hysteroscopic myomectomy, there is an overall 1.5% risk of adhesiogenesis 1-3 months after treatment for solitary myomata, but as high as 78% after resection of two or more apposing myomata. However, hysteroscopic myomectomy involves resection of extensive areas of endometrium, often including the basalis layer, whereas focal myoma ablation may or may not involve the endometrium. While some studies have looked at patients up to three months status-post hysteroscopic myomectomy, adhesions were noted as early as 1-2 weeks postoperatively and the majority of studies suggest early second-look hysteroscopy (within 1-4 weeks) for early detection and lysis of intrauterine adhesions. It should be noted that Sonata is designed to ablate target fibroid tissue and is not endometrial ablation. Unlike endometrial ablation, in which there is intentional obliteration/removal of the entire endometrium that can incite significant adhesions, the Sonata System delivers RF energy focally to ablate fibroids beneath the endometrium and does not destroy significant areas of endometrium. (Please see also Section 4 *Introduction* of the protocol)

Study objective

The objective of the OPEN Study is to document the presence or absence of intrauterine adhesions after treatment with the Sonata System when used in women with submucous and/or transmural fibroids in accordance with product labeling.

An evaluation for adhesions will be done through second look hysteroscopy.

Study design

Post-market prospective, multicenter, single-arm cohort study

Study burden and risks

Only those subjects for whom the sonata treatment was selected for the

treatment of their fibroids are being asked to participate in the trial. Thus no additional risk is associated with the Sonata treatment in this trial. Risks associated with the second-look hysteroscopy are the same as those for the baseline hysteroscopy, and there are no incremental risks associated with subsequent hysteroscopies.

Furthermore subjects will receive more medical consultations and observations than would typically occur outside this study. Early diagnosis of intrauterine adhesions at 6 weeks after treatment may permit early treatment of these adhesions.

The anticipated risk/benefit ratio of this study is favorable due to the low risks inherent with standard diagnostic hysteroscopy relative to the benefit of increased knowledge regarding the impact of transcervical RF ablation of uterine fibroids on the potential development of uterine synechiae. The rare risk of uterine perforation during second-look hysteroscopy at the 6-Week Follow-up Visit is outweighed by the potential benefits of early detection of intrauterine adhesions, such as the possibility of early treatment of adhesion-related issues and preservation of access to the endometrial cavity in the future.

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

- Have selected SONATA for treatment of fibroids in the presence of heavy menstrual bleeding
- Presence of at least one submucous myoma (type 1, type 2) or transmural fibroid (type 2-5)
- Are * 18 years of age at the time of enrollment
- Willing and able to read, understand, and sign the informed consent form and to adhere to all
study follow-up requirements

Exclusion criteria

-Preexisting adhesions within the endometrial cavity as indicated by an ESH score>=I as determined by the investigator
-one or more Type 0 fibroids and/or endometrial polyps of any size
-any reason for which, in the opinion of the Investigator, the individual study patient is not appropriate or suitable for participation in this study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-12-2017

Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	hysteroscopy (used for second-look hysteroscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-10-2017
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02844920
CCMO	NL59326.015.16