Evaluation of the Gynesonics System for Transcervical Treatment of Symptomatic Uterine Fibroids with Radiofrequency Ablation under Integrated Intrauterine Sonography Guidance

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To establish the safety and effectiveness of the Sonata System in the treatment of symptomatic uterine fibroids.

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

Summary

ID

NL-OMON43153

Source
ToetsingOnline

Brief title
Sonography-Guided Transcervical Ablation of Uterine Fibroids (SONATA)

Condition

- Menstrual cycle and uterine bleeding disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
fibroid of the uterus, myoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: leiomyoma, menorrhagia, uterine fibroids

Outcome measures

Primary outcome

(a) Reduction in menstrual blood loss (MBL) as assessed by pictorial blood loss assessment chart (PBAC)

(b) Rate of surgical reintervention for heavy menstrual bleeding (HMB) due to treatment failure

Secondary outcome

(a) Safety - adverse device effects

(b) Reduction in total and perfused fibroid volume as measured by contrast-enhanced MRI

(c) Change in the symptom severity score and health-related quality of life subscales of the Uterine Fibroid Symptom and Quality-of-Life (UFS-QOL) Questionnaire

(d) Overall subject treatment outcome using the Overall Treatment Effect Scale (OTE)

(e) Time to return to normal activity (days)

(f) Subject Satisfaction

(g) Change in general health outcome as measured with the EuroQOL EQ-5D questionnaire

(h) Subject pain and tolerance of procedure

(i) Mean institutional length of stay (LOS)

(j) Occurrence of pregnancy and pregnancy outcome

(k) Change in work productivity and activity impairment due to uterine fibroid

symptoms as measured with the Work Productivity and Activity Impairment

Questionnaire: Specific Health Problem (WPAI:SHP)

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 women of African ancestry. 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. Gynesonics has developed a device for performing minimally invasive transcervical fibroid visualization and ablation, the Sonata System. The Sonata System combines intrauterine ultrasound (IUUS) with radiofrequency (RF) ablation in a single handpiece. Sonata is suitable in an inpatient or outpatient setting, and is intended to provide focal treatment of symptomatic fibroids responsible for heavy menstrual bleeding (HMB).

Study objective

To establish the safety and effectiveness of the Sonata System in the treatment of symptomatic uterine fibroids.

Study design

Prospective, longitudinal, multicenter, single-arm cohort study with the

subject serving as her own control.

Intervention

Trans-cervical intrauterine-ultrasound-guided radiofrequency ablation.

Study burden and risks

The above listed risks and benefits are similar to those for several currently marketed device therapies for subjects with uterine fibroids, particularly other electrosurgical devices deployed hysteroscopically, laser treatment, and MR-guided high-focused ultrasound treatment. There do not appear to be any new risks with the Sonata System that would lead to an unfavorable risk/benefit ratio. Also, compared to more invasive treatment options, such as hysterectomy, laparoscopic myomectomy, laparoscopic RF ablation, and uterine artery embolization, the anticipated risk/benefit ratio for the Sonata System appears to be favorable.

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

1) Are premenopausal
2) Are * 25 and * 50 years of age at time of enrollment
3) Have experienced heavy menstrual bleeding associated with fibroids (AUB-L) for at least the previous three months as reported by the subject
4) Have * 1 and * 10 fibroids of FIGO types 1, 2, 3, 4, and/or type 2-5, with diameter * 1.0 cm and * 5.0 cm as determined by credentialed transvaginal sonography or magnetic resonance imaging (MRI). Fibroids of type 5, 6, and 7 do not count toward the clinically relevant total, irrespective of size.
5) Have at least one type 1, type 2, type 3, or type 2-5 fibroid.
6) Pictorial blood loss assessment chart (PBAC) score * 150 and * 500 during a single baseline cycle
7) Consistent menstrual cycles of between 22 to 35 days in duration that meet the following requirements for at least 4 of the last 6 menstrual cycles prior to enrollment as reported by the subject: (1) Variations in cycle length of no more than +/- 4 days, and (2) Bleeding duration of 3-10 days, in which the bleeding requires use of more than a pantiliner
8) Subject is not at material risk for pregnancy (not sexually active; has been sterilized; does not have a male partner or is in a monogamous relationship with a sterilized male partner; reliably uses barrier contraception, or oral or vaginal hormonal contraception. Subject is willing to maintain use or non-use of non-injectable hormonal contraception uniformly from 6 months pre-study through the 12-month follow-up period.1. If a subject is on oral/vaginal hormonal contraception solely for bleeding control, or if a subject does not wish to commit to 12 months of consistent hormonal contraceptive use, subject must discontinue use as per the washout period specified in Appendix H (protocol).
9) Speaks and reads a language for which validated questionnaires are available
10) Willing and able to read, understand, and sign the informed consent form, to participate in the study and to adhere to all study follow-up requirements

Exclusion criteria

1) Pregnancy, as determined by urine or serum hCG obtained within 24 hours prior to treatment with Sonata
2) Urgent need for surgery to treat fibroid symptoms
3) Desire for current or future childbearing
4) Presence of a tubal implant for sterilization
5) Postmenopausal by history
6) Presence of type 0 fibroids, unless < 1 cm in diameter and are unlikely to contribute to

bleeding in the judgment of the investigator.
7) Presence of a single polyp 1.5 cm, or multiple polyps of any size, within the uterine cavity, or excision of polyps within three months of completing any screening procedures
8) Any fibroid of FIGO type 1, type 2, type 3, type 4, or type 2-5 with diameter > 5.0 cm as determined by transvaginal sonography or magnetic resonance imaging (MRI)
9) Bulk symptoms (pelvic pressure, frequent urination) that significantly interfere with normal daily activities in the presence of one or more fibroids of FIGO type 5, type 6, or type 7
10) Exclusive presence of fibroids that, despite meeting other eligibility criteria, are insufficient to explain the severity of symptoms in the judgment of the Investigator
11) Presence of clinically relevant fibroids that cannot be treated for technical reasons (e.g. cervical fibroid)
12) Presence of an extrauterine pelvic mass that has not been diagnosed as benign
13) IUD/IUS in situ within the washout period specified in Appendix H (protocol) prior to undergoing any screening procedures
14) Not used
15) Previous procedure for fibroids or heavy menstrual bleeding other than myomectomy. Examples of excluded procedures: endometrial ablation, uterine artery/fibroid embolization, uterine artery occlusion, MR guided focused ultrasound, radiofrequency ablation.
16) Myomectomy by any route within 12 months prior to undergoing any screening procedures, or myomectomy > 12 months with less than 6 months of symptom relief
17) Any abnormality of the endometrial cavity that, in the judgment of the Investigator, obstructs access of the Sonata Handpiece to the endometrial cavity or fibroids (e.g., significant intrauterine synechiae)
18) Contraindication to MRI, including MR-incompatible implants, allergy to contrast media or claustrophobia, and weight that is above the limitation of the site-specific MRI scanner credentialed for the study
19) Total uterine volume * 1000 cc as determined by transvaginal sonography
20) Clinically significant adenomyosis based on sonography; presence confirmed by MRI (defined as more than 10% of the junctional zone measuring more than 10 mm in thickness as measured by MRI)
21) Confirmed or suspected diagnosis of clinically relevant endometriosis
22) One or more clinically relevant fibroids that are significantly calcified. If suspicion of calcification, refer to MRI. (Significant calcification is defined as being associated with a majority of the fibroid not showing enhancement on volume via contrast-enhanced MRI)
23) Previous pelvic irradiation
24) Not used
25) Renal insufficiency [serum creatinine * 1.5 mg/dL (132.6 *mol/L)]
26) Evidence of disorders of hemostasis (AUB-C) as assessed through structured interview and confirmed by hematologic evaluation consistent with a coagulopathy (see Appendix D)
27) Abnormal cervical cytology that is unevaluated or untreated in adherence with national guidelines
28) Endometrial hyperplasia (AUB-M), including simple hyperplasia without atypia, as determined by an endometrial biopsy within 12 months prior to enrollment
29) Confirmed abdominal / pelvic malignancy within the previous five years
30) Active pelvic infection (e.g., active salpingitis or other pelvic inflammatory disease) or current positive testing for pelvic gonorrhea or chlamydia; entry into the study would require a test of cure after treatment

31) Use of a GnRH agonist, depomedroxyprogesterone acetate or other hormonally-relevant medication within the washout period as specified in Appendix H prior to undergoing any screening procedures
32) Use of an antifibrinolytic agent while undergoing any screening procedures.
33) Current use of anticoagulant therapy (warfarin derivatives or heparin)
34) Chronic pelvic pain (disruptive for at least six months) or baseline pelvic or menstrual pain > 6 as captured using the Numeric Rating Scale (NRS-11) as shown in Appendix J.2
35) Chronic uncontrolled moderate and severe hypertension. (Chronic mild hypertension may be enrolled after obtaining medical clearance from a physician not participating in the study.)
36) A hypoplastic or otherwise short uterus (distance from the top of the endometrial cavity to the external cervical os < 4.5 cm, as determined by transvaginal sonography or prior uterine sounding)
37) Major medical or psychiatric illness or other factors that, in the judgment of the Investigator may affect general health or subject*s ability to adhere to the follow-up schedule or provide valid subject self-assessment data
38) Any other reason for which, in the opinion of the Investigator, the individual study subject is not appropriate or suitable for participation in the clinical trial

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2016
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	SONATA system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-07-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-08-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	30-08-2016
Application type:	Amendment
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	NCT02228174
CCMO	NL57107.015.16