Symptom Effectiveness Study of VizAblate® Intrauterine Ultrasound-Guided RF Ablation (IUUSgRFA) in the Ablation of Large Uterine Fibroids

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The objective of this study is to establish the effectiveness and confirm the safety of the VizAblate System in the ablation of large (> 5 cm) symptomatic uterine fibroids.

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

Summary

ID

NL-OMON39138

Source
ToetsingOnline

Brief title
Fibroid Ablation Study - Large Fibroids (FAST-L)

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
fibroid of the uterus, myoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Leiomyoma, Menorrhagia, Uterine fibroids

Outcome measures

Primary outcome

(a) Mean percentage change in target fibroid perfused volume

Secondary outcome

(a) Safety (to include procedural safety and long-term safety, including specifically following subjects for the occurrence of pregnancy and pregnancy complications)

(b) Percentage reduction in Symptom Severity Score (SSS) subscale of the Uterine Fibroid Symptom and Quality-of-Life (UFS-QOL) Questionnaire

(c) Rate of surgical reintervention for menorrhagia

(d) Mean return to normal activity (days)

(e) Percentage reduction in Menstrual Pictogram score

Study description

Background summary

Uterine fibroids or myomas 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 Caucasians 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 (menorrhagia), 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 new technique for performing minimally invasive transcervical fibroid tumor visualization and ablation. The technique uses the VizAblate System, which has obtained CE-marking and which is a novel approach that combines intrauterine ultrasound (IUUS) with radiofrequency (RF) ablation in a single device. VizAblate appears to be suitable for the operating room, ambulatory surgical center or office and is intended to provide focal treatment of symptomatic submucous and intramural fibroids responsible for menorrhagia.

A separate clinical trial (CL 02413 *FAST-EU* trial) is ongoing and is intended to gather data regarding the effectiveness and to confirm safety of the VizAblate treatment on the treatment of symptomatic uterine fibroids in the range 1 cm - 5 cm. This parallel clinical trial is intended to gather similar data related to treatment of symptomatic uterine fibroids, including those with diameters in the range > 5 cm -10 cm.

Study objective

The objective of this study is to establish the effectiveness and confirm the safety of the VizAblate System in the ablation of large (> 5 cm) symptomatic uterine fibroids.

Study design

Prospective, longitudinal, multicenter, single-arm cohort study with the subject serving as her own control.
Up to 15 investigational sites in the Netherlands, United Kingdom, and Mexico will participate in this study.

Intervention

VizAblate Intrauterine Ultrasound-Guided RF Ablation (IUUSgRFA)

Study burden and risks

VizAblate Procedure Risks - Risks associated with the use of the VizAblate System are expected to be similar to complications associated with hysteroscopic myoma resection and electrosurgical procedures. Note that as the IUUS imaging does not involve distension of the uterus, the risks of fluid overload applicable to hysteroscopic myoma resection would not apply to the VizAblate procedure. Based on clinical development work under study CL00763, the maximum amount of hypotonic fluid utilized to date in a single procedure is 360 cc, and the mean is 110 cc. Abdominal pain, nausea, vomiting, pelvic pain and cramps, bleeding, urinary tract infection, vaginal discharge and vaginal bleeding and spotting are common side effects of this type of surgery and expected to occur in approximately 40% of patients. There is a small chance that a dead piece of fibroid may be expelled after treatment from the uterus

and vagina. The chance of this happening is very small (we estimate no more than 0.1% of cases) and has not been reported after any treatment similar to VizAblate. Passage of a treated fibroid has been reported after uterine artery embolization and there is one report of fibroid passage after treatment with a different device that uses radiofrequency current to destroy the entire lining of the womb. If a piece of fibroid is expelled, one sees perhaps a clot the size of a marble or larger, or a mass in the vagina. This is perhaps associated with cramps. If this happens, one should immediately contact the study physician for further evaluation. Passing a treated fibroid is normally no significant health risk, but in some cases could require removal of any remaining tissue and / or a treatment of any infection.

Prior to the start of the FAST-EU clinical study, the VizAblate procedure has been performed in more than 75 patients immediately prior to hysterectomy and in approximately 20 patients up to 2 weeks prior to hysterectomy to evaluate procedure safety. Additional known possible adverse events, side effects (unwanted effects or health problems) and discomforts that may be associated with the VizAblate procedure, surgery, and anesthesia, with frequency of occurrence based on similar procedures where known, include: cut/narrowed/blocked/torn/perforated cervix or uterus (less than 1 in 100), damage to nearby organs, bubble of air/gas/fluid entering the blood system, deep vein thrombosis, pulmonary embolism (blood clot in the lungs; 4 in 1000), myocardial infarction (heart attack), inflammation of the endometrium (lining of the uterus), breathing difficulties, blood clotting problems, fever, blood caught in the uterus (due to blocked cervix), infection or sepsis (infection of the blood), tubal ovarian abscess, blocked fallopian tube/s, allergy or sensitivity to anesthetic drug (approximately 1 in 3500), slow heart rate, breathing arrest, electrical/thermal burn. Outcomes of these complications may be severe, including death. Severe or life-threatening complications, however are very uncommon.

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

(a) 28 years of age or older
(b) Consistent menstrual cycles between 22-35 days
(c) History of excessive bleeding for at least 3 months
(d) Baseline UFS-QOL SSS score >= 20
(e) At least one Target Fibroid having a maximum diameter > 5 cm and
<= 10 cm
(f) Total Target Fibroid Score <= 45
(g) Subject is not at material risk for pregnancy (not sexually active, does not have a male partner or is in a monogamous relationship with a sterilized male partner, using reliable oral or barrier contraception, intrauterine device (IUD) or the levonorgestrel intrauterine system (LNG-IUS) in accordance with the package insert). Subject is willing to maintain use or non-use of hormonal contraception uniformly from 3 months pre-study through the 12-month follow-up period. Only monthly cyclic combined contraceptive steroids will be acceptable as oral contraception.
(h) Willingness to participate in the study, to adhere to all study follow-up requirements, and to sign the informed consent form
(i) Subject is willing to have uniform maintenance (use or non-use) of any antifibrinolytic or nonsteroidal anti-inflammatory agents (COX inhibitors) for excessive vaginal bleeding for 2 months pre-study through the 12-month follow-up period
(j) Menstrual Pictogram score >= 120 during a one-month screening period.

Exclusion criteria

(a) Presence of type 0 intracavitary fibroids
(b) Any Target Fibroid > 10 cm in maximum diameter

(c) Any abnormality of the endometrial cavity that, in the judgment of the investigator, obstructs access of the VizAblate Handpiece to the endometrial cavity.
(d) Postmenopausal by history
(e) Desire for current or future fertility
(f) Hemoglobin < 6 g/dl (3.7 mmol/L)
(g) Pregnancy, as determined by urine hCG obtained within 24 hours prior to VizAblate procedure
(h) Evidence of disorders of hemostasis
(i) Use of GnRH agonist or depomedroxyprogesterone acetate or other implantable or injectable progestin and/or estrogen, SERM or SPRM within the last 6 months prior to completion of screening UFS-QOL.
(j) Evidence for current cervical dysplasia (CIN II or greater)
(k) Endometrial hyperplasia
(l) Confirmed abdominal / pelvic malignancy within the previous five years
(m) Active pelvic infection (e.g., active salpingitis or other pelvic inflammatory disease) or positive screening for pelvic gonorrhea or chlamydia
(n) Clinically significant adenomyosis
(o) Previous uterine artery embolization
(p) Previous surgical or ablative treatment for fibroids or menorrhagia within 12 months prior to completion of the screening UFS-QOL.
(q) Current use of anticoagulant therapy
(r) Need for emergency surgery to treat fibroid symptoms
(s) Major medical or psychiatric illness affecting general health or subject*s ability to adhere to the follow-up schedule or provide valid subject self-assessment data
(t) Contraindication to MRI, including allergy to contrast media or claustrophobia
(u) Renal insufficiency [serum creatinine >= 1.5 mg/dL (132.6 µmol/L)]]
(v) Uncontrolled hypertension lasting 2 years or more (systolic blood pressure >= 140 mm Hg and/or diastolic blood pressure >= 90 mm Hg that is not controlled with an antihypertensive drug regimen)
(w) One or more treatable fibroids that are calcified
(x) Chronic pelvic pain (disruptive for at least six months)
(y) Presence of an extrauterine pelvic mass
(z) Presence of a tubal implant for sterilization
(aa) Previous pelvic irradiation
(bb) Endometrial cavity length < 4.5 cm

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2013
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	VizAblate System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-07-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO

Date:	08-02-2013
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	NCT01539187
CCMO	NL40365.015.12