

Protocol Registration Receipt

02/12/2010

Grantor: CDRH IND/IDE Number: G080163 Serial Number: I070371

Laparoscopic Radiofrequency Ablation of Symptomatic Uterine Fibroids (Halt Lap RFA)

This study is currently recruiting participants.

Verified by Halt Medical, Inc, February 2010

Sponsor:	Halt Medical, Inc
Collaborators:	
Information provided by:	Halt Medical, Inc
ClinicalTrials.gov Identifier:	NCT00874029

Purpose

The purpose of this study is to demonstrate the safety and effectiveness of radiofrequency ablation (RFA) using the Halt System for the treatment of patients with symptomatic uterine fibroids.

Condition	Intervention	Phase
Uterine Fibroids Uterine Myomas	Device: Halt System	N/A

Study Type: Interventional

Study Design: Treatment, Single Group Assignment, Open Label, Non-Randomized, Safety/Efficacy Study

Official Title: Evaluation of the Halt System for Laparoscopic Treatment of Symptomatic Uterine Fibroids With Radiofrequency Ablation

Further study details as provided by Halt Medical, Inc:

Primary Outcome Measure:

- Menstrual bleeding at 12 months compared to pre-procedure (baseline) [Time Frame: 12 months from Baseline] [Designated as safety issue: No]

- Incidence of device and procedure-related adverse events within 12 months post-procedure [Time Frame: 12 months] [Designated as safety issue: No]
- Surgical re-Intervention for menorrhagia at 12 months [Time Frame: 12 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- Uterine and fibroid volume at 12 months post-procedure compared to pre-procedure (baseline) as measured with contrast-enhanced MRI (magnetic resonance imaging) [Time Frame: 12 month from Baseline] [Designated as safety issue: No]
- Fibroid Symptom severity and quality of life at 12 months post-procedure as compared to pre-procedure (baseline) using the Uterine Fibroid Symptom and Health Related Quality of Life (UFS-QoL) assessment tool. [Time Frame: 12 months] [Designated as safety issue: No]
- General health outcome at 12 months post-procedure as compared to pre-procedure using the EQ-5D (a standardized instrument for use as a measure of health outcome) [Time Frame: 12 months] [Designated as safety issue: No]
- Overall subject treatment outcome and satisfaction using the Overall Treatment Evaluation (OTE) [Time Frame: 12 months] [Designated as safety issue: No]

Estimated Enrollment: 150

Study Start Date: March 2009

Estimated Study Completion Date: December 2012

Estimated Primary Completion Date: October 2010

Number of arms: 1

Intervention Details:

Device: Halt System

The Halt 2000 System™ (also called the “Halt System”) is a Radiofrequency Generator with its accessories that is designed to deliver monopolar radiofrequency (RF) energy to tissue through a hand-held disposable RF Probe.

In this single-arm study, subjects who have symptomatic uterine fibroids will have laparoscopic surgery in which intra-abdominal ultrasound will guide RF ablation of uterine fibroids using the Halt System.

Eligibility

Ages Eligible for Study: 25 Years and older

Genders Eligible for Study: Female

Accepts healthy volunteers.

Inclusion Criteria:

- Are premenopausal and ≥ 25 years old
- Have symptomatic uterine fibroids
- Have a uterine gestational size ≤ 14 weeks as determined by pelvic exam
- Have ≤ 6 (six) treatable fibroids in whom no single fibroid exceeds 7 cm in any diameter as measured by ultrasound or magnetic resonance imaging (MRI). Only Fibroids greater than 1cm in diameter should be

treated in this study.

- Have a total uterine fibroid volume that does not exceed 300cc on ultrasound or contrast-enhanced MRI evaluation
- Have clinical menorrhagia as indicated by menstrual blood loss of ≥ 160 mL to 500 ml during one baseline cycle or two baseline cycles within three months prior to treatment.
- Have a history of at least 3 months of menorrhagia within the last six months.
- Desire uterine preservation
- Do not desire current or future childbearing
- Have a normal coagulation profile (INR, Platelets, PT, and PTT)
- Have had a normal Pap smear within the past 12 months
- Are practicing non-hormonal or stable hormonal contraception
- If the woman is not currently taking any hormonal contraceptives, has been off all hormonal contraceptives for a minimum of three months prior to study enrollment, and agrees to continue without change in regimen through the 12 months of follow-up. or
- If the woman is currently taking hormonal contraceptives, has taken hormonal contraceptives for a minimum of three months prior to study enrollment, and agrees to continue without change in regimen through 12 months of follow up.**

**Note: Hormonal contraceptive use must be terminated 30 days prior to treatment but should be resumed post-operatively within 60 days post treatment as instructed by the Investigator.

- Are willing and able to comply with all study tests, procedures, and assessment tools
- Are willing and able to return for all required follow up visits following study enrollment
- Must pass a pre-operative health exam (ASA I-III)
- Are capable of providing informed consent

Exclusion Criteria:

- Have contraindications for laparoscopic surgery and/or general anesthesia. (Contraindications include anemia, defined as a hemoglobin level under 10 or hematocrit level less than 30.)
- Have had prior pelvic surgery (with the exception of C-section, tubal ligation, or diagnostic laparoscopy), or are known to have significant intra-abdominal adhesions (defined as adhesions that would require extensive dissection to mobilize and view all surfaces of the uterus)
- Have previously undergone endometrial ablation, uterine artery embolization, or uterine artery ligation, or any other uterine-preserving technique for reduction of menstrual bleeding (with the exception of hysteroscopic myomectomy > 1 year ago)
- Patients requiring elective concomitant procedures
- Have contraindications for magnetic resonance imaging (MRI)
- Desire current or future childbearing
- Are pregnant or lactating
- Have taken any GnRh agonist within three months prior to the screening procedures
- Have an implanted intrauterine or fallopian tube device for contraception that cannot or will not be removed one month prior to treatment
- Have dysfunctional uterine bleeding or bleeding between periods
- Have chronic pelvic pain not due to uterine fibroids
- Have known or suspected endometriosis
- Have known or suspected adenomyosis based on Ultrasound or MRI findings

- Have active or history of pelvic inflammatory disease
- Have a history of or evidence of gynecologic malignancy or pre-malignancy within the past five years
- Have had pelvic radiation
- Have a non-uterine pelvic mass
- Have a cervical myoma
- Have one or more pedunculated subserosal fibroids or "type zero" (completely intracavitary) submucous fibroids
- Are peri-menopausal (defined as women 40 years of age or older with FSH level of ≥ 25 IU) or menopausal.
- Are unable to give informed consent
- In the medical judgment of the investigator should not participate in the study

Contacts and Locations

Contacts

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Locations

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Investigators

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More Information

Responsible Party: Halt Medical, Inc. (Anais Laborde/Sr. Mgr, Clinical Affairs)
Study ID Numbers: CP-00-0004
Health Authority: United States: Food and Drug Administration