SOFIA Clinical Trial

MR-HIFU of Uterine Fibroids

Uterine fibroids are extremely common benign tumors occurring in 20-50% of women over 30 years of age. Depending on location and size, fibroids can produce very unpleasant symptoms for a patient including pain, heavy menstrual bleeding, pressure, bloating and urinary and bowel compression. Symptomatic fibroids impact a woman's health and well-being in both lost work hours and reduced quality of life.

Current medical treatments include surgical removal of the fibroid, with hysterectomy still the most common surgical procedure for fibroids and drug therapy or other modalities being used less frequently. Surgical procedures often require anesthesia, hospital stays, and long recovery periods. For symptom relief, women wishing to preserve the uterus may choose less invasive procedures, such as myomectomy or uterine artery embolization (UAE).

Objective of this study

The objective of this clinical trial is to compare the safety and clinical effectiveness of a non-invasive MR-HIFU Fibroid Therapy system for relief from uterine fibroids to the alternative of no treatment. The trial is being conducted for the purposes of regulatory approval in the USA.

Why participate in a clinical trial?

The U.S. National Institutes of Health says that patients should participate in a clinical trial because "participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available and help others by contributing to medical research." Clinical trials are an important part of advancing medical care.

PHILIPS

Who is eligible to participate?

All clinical trials have guidelines about who can participate, which are called Inclusion/Exclusion criteria. Your physician should review all of these guidelines with you in detail, but generally, this study should include pre- or peri-menopausal women between 18-50 years of age suffering from symptomatic uterine fibroids (including heavy menstrual bleeding), who fit the criteria following medical screening – and importantly, are willing and able to attend all study visits and complete follow-on materials.

What to expect

Eligibility

If you are eligible for this study based on the screening with your physician, you will be put into one of two groups by chance (as in the flip of a coin). This is called randomization. Since you will be assigned to either the MR-HIFU group or the no-treatment group by chance, you will not be able to choose whether you receive MR-HIFU or no treatment, yet the majority of patients will enter the MR-HIFU group.

About MR-HIFU

MR-HIFU takes place in a MRI machine equipped with an ultrasound device. Ultrasound waves go through the abdominal wall to non-invasively heat and destroy the fibroid. No incisions are made and each fibroid is targeted separately. Some fibroids cannot be treated with this technique, due to fibroid location and type. Part of the screening for the clinical trial includes screening to determine if you are a suitable candidate for the MR-HIFU procedure. Your doctor will explain the screening process and the procedure in detail.

Follow-up

As a participant in this study, you will need to complete several visits with the investigator and complete several questionnaires and assessments about your general health and fibroid symptoms. You will be scheduled for investigator visits at 3, 6 and 12 months after treatment and additionally asked to complete the questionnaires before and just after you receive treatment and periodically during the 12, 24 and 36 months following treatment.

You will receive compensation for your time.

How long is the study?

Patients will be followed for three years after MR-HIFU treatment.

Who can I contact for additional information?

You can gain full information about the trial and treatment sites on the National Institutes of Health website: **www.clinicaltrials.gov** by searching for the study identifier: NCT01504308.

In addition, you can contact a site near you at:

(Contact Name)

(Site Name)

Phone:

Email:

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