

PARKINSON'S DISEASE

Parkinson's disease (PD) is a chronic, degenerative, neurologic disorder caused by the death of nerve cells in the brain. As the disease progresses, many patients develop symptoms such as dyskinesia and motor fluctuations that are difficult to manage effectively. Dyskinesia is involuntary movements that can become disabling and are a common complication of PD treatment with drugs such as levodopa.

+ CURRENT TREATMENT OPTIONS FOR PARKINSON'S DISEASE

- **Medications** – you could continue to receive medications.
- **Surgery** – a surgical procedure, called a pallidotomy, can be performed on one side of the brain by other methods than with the ExAblate Neuro. This procedure involves destroying brain tissue in a part of the brain called the *globus pallidum* and has been shown to reduce PD symptoms.
- **Deep Brain Stimulation (DBS)** – when patients no longer benefit from medication, DBS may be considered. DBS of the *globus pallidum* or the *subthalamic nucleus* can be performed bilaterally (on both sides of the brain). The procedure involves implanting an electrical device in your chest with 1 or 2 electrodes in your brain.

+ HOW LONG WILL I BE IN THE STUDY?

After the ExAblate Neuro procedure, six follow-up visits will be completed during a one year period. You will have scheduled visits at 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year after treatment to monitor the success of the procedure.

+ HOW CAN I FIND OUT MORE?

If you have questions or are interested in participating, please contact:

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Additional information is available at:
www.clinicaltrials.gov
NCT03319485

+ ABOUT EXABLATE

Exablate Neuro is an innovative medical device that uses focused ultrasound together with MR imaging to precisely target and treat a small area deep within the brain through an intact skull.



Do you have
Dyskinesia
Symptoms or
Motor
Fluctuations
associated
with
advanced
Parkinson's
Disease?

If you have advanced Parkinson's disease and are experiencing dyskinesia symptoms or motor fluctuations that are not responding to medicines, you may be eligible for a clinical trial examining a new minimally invasive method to treat your symptoms.

INSIGHTEC
Therapy In Focus

WCMC IRB	
Approval Date:	01/02/2018
Expiration Date:	12/03/2018

Introduction



+ WHAT IS EXABLATE NEURO MR guided FOCUSED ULTRASOUND?

ExAblate MRgFUS, a minimally invasive treatment, uses focused ultrasound waves to destroy tissue within the targeted area in the brain using a transcranial (through the skull) approach.

During the treatment you lie in an MRI scanner (a special system that provides very detailed images of the brain and surrounding anatomy). The MRI helps the physician "see" inside the body to pinpoint, guide, and continuously monitor the treatment.

The focused ultrasound energy is directed at a small group of cells called the *globus pallidum* in the brain. Ultrasound beams are focused through the skull and into the brain similar to a magnifying glass focusing sunlight on paper. Only the spot where the beam is focused gets hot enough to be destroyed during the sonication lasting about 20 seconds, creating a spot about the size of a coffee bean. The delivery of energy is called a 'sonication' and should not affect other parts of the body. Multiple sonications may be delivered until the targeted area is treated.

+ WHAT ARE THE BENEFITS OF EXABLATE NEURO MRgFUS SYSTEM?

- It is minimally invasive, so no incisions are needed
- There is no radiation
- The MRI guidance provides anatomical placement and temperature monitoring in real-time as the treatment is being delivered.

The full benefits of this treatment will be evaluated through this study.

+ WHAT ARE SOME OF THE RISKS OF THE PROCEDURE?

ExAblate Neuro could cause temporary pain, headache, nausea/vomiting, and slurred or slow speech as a result of swelling in the treated area. There is the possibility of damage to other tissue, but this is minimized through MR imaging which shows the exact location of the focused ultrasound. There may be other risks that your doctor will discuss with you.

+ WHAT IS THE PURPOSE OF THIS STUDY?

The goal of this investigational study is to evaluate the safety and effectiveness of MR guided Focused Ultrasound (MRgFUS) using the ExAblate Neuro system to perform a pallidotomy on one side of the brain to treat motor symptoms of Parkinson's disease (PD).

+ HOW LONG DOES THE PROCEDURE TAKE?

The entire ExAblate Neuro MRgFUS procedure may take up to four hours.

+ WHO CAN PARTICIPATE?

Patients who:

- Men and women, age 30 years and older
- Have motor complications of PD on optimum medical treatment
- Are able to undergo MR imaging
- Are responsive to the drug levodopa
- Have not had previous PD surgery or DBS

Other criteria will be explained by your doctor.

+ WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

You will undergo clinical evaluation of your PD symptoms and an MRI scan to determine if you qualify for the study. If you are eligible and agree to be in this study, you will be treated with ExAblate and followed up for 12 months for treatment outcome, including safety and effectiveness. You will need to complete questionnaires multiple times during the study.

+ WHAT IS THE COST?

There is no cost to you for the investigational treatment procedure.

