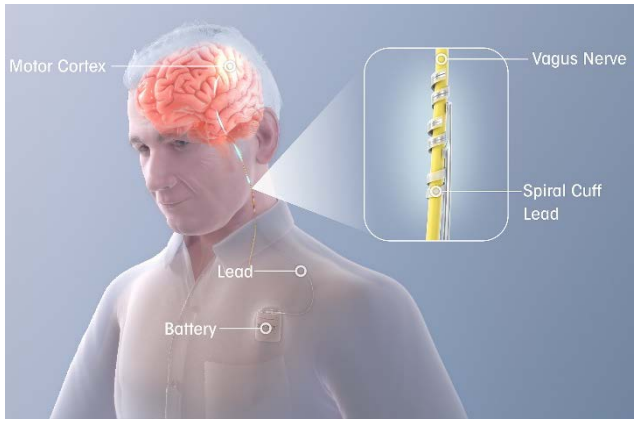
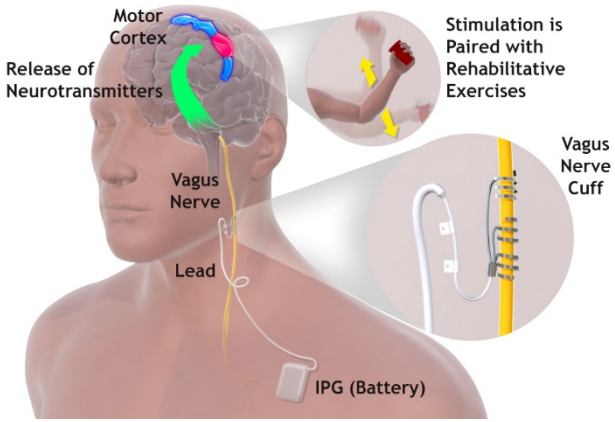
Diagram of Vivistim® System used in Clinical Trial



This clinical trial uses an implantable device (called the Vivistim® System), which is placed insude your body during an outpatient surgical procedure.



WCMC IRB
Approval Date: 6/26/18
Expiration Date: 6/25/19

MicroTransponder®

Vivistim® SYSTEM

MicroTransponder is a medical device company with an expert team of neuroscientists and engineers who have worked with doctors to develop a neurostimulation system to treat people with stroke. Decades of research have led to this new, unique therapy for the treatment of stroke.

If you are interested in more information regarding Stroke Rehabilitation, please visit: http://www.ninds.nih.gov/disorders/stroke/stroke_rehabilitation.htm

National STROKE Association™

To visit the Clinicaltrials.gov page for the trial:

https://clinicaltrials.gov/show/NCT03131960

CAUTION – Investigational device. Limited by United States law to investigational use. Not for Sale in Europe or U.S.

VNS Stroke Trial

Study Participants

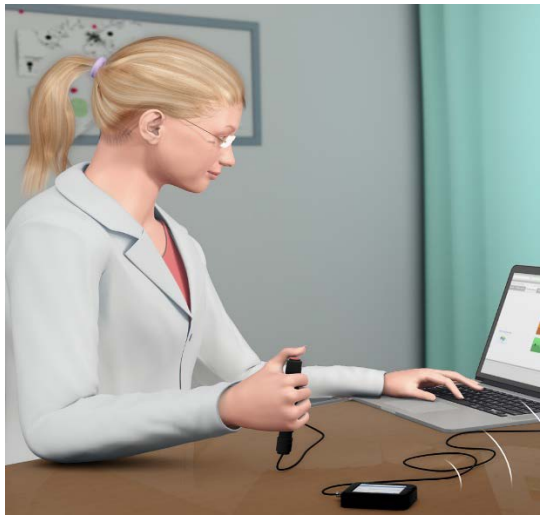
The Vivistim® System clinical trial for the treatment of stroke is open to all U.S. residents between the ages of 22 and 80 who have had a stroke at least 9 months ago but not more than 10 years ago.

The Vivistim® System has been developed by MicroTransponder to treat arm and hand problemsin people who have had a stroke.

The Vivistim® System combines an existing therapy called Vagus Nerve Stimulation (VNS) with rehabilitative occupational therapy.

VNS has been used in the U.S. to treat over 100,000 people with epilepsy and depression.

www.vnsstroketrial.com



About the Study

The Vivistim® System clinical trial for the treatment of stroke is open to all U.S. residents between the ages of 22 and 80 who have had a stroke at least 9 months ago but less than 10 years ago. There are many sites across the U.S. and total of 120 total subjects that will be enrolled in this trial.

This clinical trial uses an implantable device (called the Vivistim® System), which will require an outpatient procedure to place the device inside your body.

How it works

The device is fully implantable and is designed to be used with rehabilitative physical therapy. The image above depicts a VNS paired therapy session with a stroke study subject and an occupational therapist.

The study subject does a series of tasks aimed at rebuilding circuits in the brain that are responsible for upper limb movement. Each time the subject performs a movement, the therapist pushes a button and the transmitter sends a signal to the implanted device to stimulate the vagus nerve. Subjects may not feel stimulation or only notice a tingling in their neck; therapy is done over several weeks to try to improve the ability to perform daily activities.

Enrollment Criteria

Do you fulfill the following criteria?

1. I am 22 to 80 years of age
2. I had a non-bleeding stroke at least 9 months ago but not more than 10 years ago
3. I have some arm and hand movement difficulties, but can still move my hand (the site will perform specific tests to determine if you meet this criteria)
4. I don't have any speaking, or thinking difficulties that would hurt my ability to be in the study
5. I don't have any significant sensory problems
6. I don't have any aspiration or swallowing difficulties
7. I don't have any hand spasms

There are other criteria that will be checked at screening, but if you meet ALL of the criteria above, please contact us and a representative from the study site will reach out to you for an initial screening call.

Contact Us in the NYC Area:

Ruchi Patel, OTR/L

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Weill Cornell Medical College Department of Rehabilitation Medicine NewYork-Presbyterian The University Hospital of Columbia and Cornell

Do you have **arm weakness** post-stroke?

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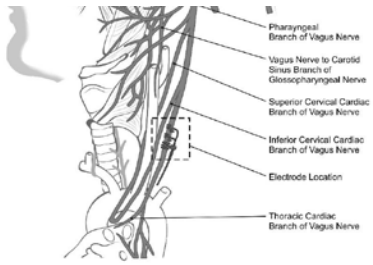

Patients with an non bleeding stroke that are between 9 months and 10 years post-stroke are invited to take part in a pivotal clinical trial to study the effectiveness of the Vivistim System® investigational device. The device is placed inside the body during an outpatient procedure and, using an external control, delivers electrical stimulation to the vagus nerve. Initial studies have shown that electrical stimulation to the vagus nerve improves recovery by increasing the brain's ability to learn & change after stroke. All subjects are implanted with the Vivistim System® and then randomized to either the immediate study treatment or the delayed active-control treatment group. Both groups will receive standard of care occupational therapy. The aim of this study is to determine the effects of the stimulation on rehabilitation.

To be eligible for participation, you must:
-Be between the ages of 22-80 and have a history of non bleeding stroke at least 9 months but not more than 10 years prior to consent
-Experience upper extremity weakness due to stroke

Subjects will be required to participate in therapy and up to three years of follow-up. Subjects will be compensated for completed study visits.

IRB Protocol # 1704018133

For further information, please contact Ruchi Patel in the Rehabilitation Medicine Dept. at 212-746-1356.

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