VNS-REHAB

Clinical Trial

Currently recruiting participants

Start Date: July 1, 2017
End Date: June 30, 2019

For more information, please contact

Zoe Tsagaris
kzt3001@med.cornell.edu
914.597.2153

Trial Identifier: NCT03131960
Lab: Human Motor Control Laboratory

Principal Investigator:
Tomoko Kitago, M.D.
Study Coordinator and Clinical Research Therapist :
Zoe Tsagaris, MS, OTR/L

What Do We Do?

We are looking for volunteers to undergo a six-week session of intensive rehabilitation therapy. There will be three sessions each week, each session of rehabilitation therapy will last about one hour. The therapy sessions will include traditional rehabilitation exercises, but the patient will receive nerve stimulation while they are performing the exercises.

How Do Patients Qualify for the Study?

If you are 21-80 years old, have had an ischemic stroke (caused by a blood clot) that occurred at least 9 months but no more than 10 years ago, and experience residual arm or hand weakness, then you may qualify for the study.

How Much Does It Cost?

FREE OF CHARGE

Timeline of Study

Visit 1 & 2: Screening Visit and pre-implantation visit
Visit 3: VNS implant
Visit 4: Pre-Therapy Baseline
Visits 5-22: 18 Treatment Sessions
Visits 23-25: Follow Up Assessments

If you receive a placebo or "sham" VNS during the treatment sessions, we will have you wait 3 months and return for another stage of complimentary therapy (18 sessions) with the active VNS.

Eligibility

AGE RANGE: 21-80 years old
INCLUSION CRITERIA:

- Are 21-80 years old.
- Have had an ischemic stroke (caused by a blood clot) that occurred at least 9 months but no more than 10 years ago.
- Experience residual arm or hand weakness.

If you are a stroke survivor, or know someone who has had a stroke, but do not qualify for this study, we ask that you still complete and send us your information. We offer other programs that you or someone you know may be eligible for.

Burke Neurological Institute | Weill Cornell Medicine

Learn more at **burke.weill.cornell.edu/clinical-trials**

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PATIENT DEMOGRAPHIC INFORMATION

Patient Name: _____

Address: _____

Phone: _____ **DOB/Age:** _____ **Medical Record/ID #:** _____

Emergency Contact: _____

Please check off the following:

Are you a Veteran? ☐ Yes ☐ No **Handedness:** ☐ Right ☐ Left

Body weakness: ☐ Right ☐ Left **Stroke Type:** ☐ Ischemic (Blood Clot) ☐ Hemorrhagic

Stroke Date: _____ **Stroke Number:** _____

Lesion location (if known): ☐ Cortical ☐ Subcortical ☐ Mixed ☐ Other

Co-Morbid Diseases/Pertinent Medical Conditions: _____

Pharmacological Treatment/Medication: (Please list or provide a copy)

Demographic Data	Yes	No
Smoker		
Ex-Smoker		
Current Alcohol Use		
High Cholesterol		
Diabetes Type I or II		
Previous Stroke or TIA		
Hypertension/High Blood Pressure		
Family History of Stroke		
Atrial Fibrilation (including paroxysmal)		
Implanted Metallic Parts or Implanted Electronic Device (incl. pace maker, defibrillators, medication pump, brain stimulator, aneurysm clip)		
Pregnant or Trying to Become Pregnant		
Significant Mental Illness		
History of Seizure		
Injection of Botulinium Toxin in Affected Upper Limb in Last 3 months		
Injection of Phenol in Affected Upper Limb in the last 6 months		
Currently Receiving Physical, Speech, and/or Occupational Therapy Services		

Diagnostic Testing (please check one): ☐ CT Scan ☐ MRI ☐ Other

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Non-Invasive Stimulation (TMS) Screening Questionnaire

Participant Initials: _____ **Date: ____/_____/_____**

Have you ever:

Had TMS before?	☐ Yes	☐ No
Had an adverse reaction to TMS?	☐ Yes	☐ No
Had a seizure?	☐ Yes	☐ No
Does anyone in your family have epilepsy?	☐ Yes	☐ No
Had an unexplained loss of consciousness?	☐ Yes	☐ No
Had a serious head injury?	☐ Yes	☐ No
Had any other brain related, neurological illnesses?	☐ Yes	☐ No
Do you suffer from frequent or severe headaches?	☐ Yes	☐ No
Do you have any metal in your head (outside the mouth)?		
Ex: shrapnel, surgical clips, or fragments from welding	☐ Yes	☐ No
Do you have any implanted medical devices?		
Ex: cardiac pacemakers or medical pumps	☐ Yes	☐ No

For any "Yes" responses, please provide detailed information below:

_____ **Date: ____/_____/_____**

Subject Signature

_____ **Date: ____/_____/_____**

Investigator Signature

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