

# VNS-REHAB

## Clinical Trial

Currently recruiting participants

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

For more information,  
please contact

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**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.*

Learn more at [burke.weill.cornell.edu/clinical-trials](http://burke.weill.cornell.edu/clinical-trials)

**Burke Neurological Institute** | Academic Affiliate of Weill Cornell Medicine  
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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:** \_\_\_\_\_

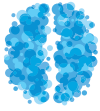
**Lesion location (if known):**  Cortical  Subcortical  Mixed  Other

**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 Fibrillation (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



## 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:

\_\_\_\_\_  
Subject Signature

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_\_  
Investigator Signature

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_