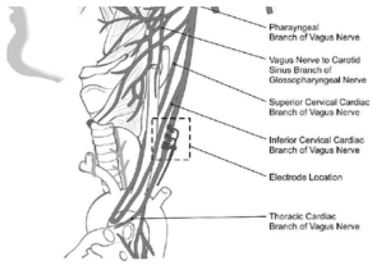
Weill Cornell Medical College

Department of Rehabilitation Medicine

NewYork-Presbyterian
The University Hospital of Columbia and Cornell

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

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



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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