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Protocol Level
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Vivistim Registry for Paired VNS Therapy

The GRASP Registry is a database of information on patients considering Paired Vagus Nerve Stimulation (Paired VNS™) Therapy with the Vivistim® System, an FDA-approved device used to help improve hand and arm function after a stroke.

The purpose of the Vivistim Registry for Paired VNS Therapy (GRASP) is to gather real-world information on patients with arm and hand deficits post-stroke who are considering Vivistim System treatment. Before and after the Vivistim System procedure, patient data will be collected and reported throughout the therapy process.

Most patients entered into the GRASP Registry will go on to be implanted with the Vivistim System although those who decide not to move forward with the implant procedure can still have data collected as a non-implant comparison group (as long as data from the same assessments are collected). The primary purpose of the GRASP Registry is to provide real-world usage and outcomes data on the Vivistim System. The patient outcome Registry will collect acute and long-term follow-up data on Vivistim implanted patients treated with Paired VNS Therapy after FDA approval.

Historical and implant information, as well as quality of life information will be gathered on patients who consider implant of the Vivistim System. Data will be collected at baseline, 3, 6, and 12 months after implantation, and then yearly thereafter for up to 3 years post-implant. Patients who decide not to have the Vivistim System implanted can continue to have data collected for comparison purposes.

Frequently Asked Questions



Q: Who is eligible for the GRASP Registry?

A: A person who meets the requirements for Paired VNS Therapy and the Vivistim implant is eligible for the GRASP Registry.

Q: Why should a patient who has been implanted participate? What will the data be used for?

A: The information collected will provide real-world usage and outcomes data on the Vivistim System. The GRASP Registry will collect acute and long-term follow-up data on Vivistim implanted patients treated with Paired VNS. Such information can then be used to help other stroke survivors' rehabilitation and recovery.

Q: How does someone who is considering the implant sign-up to participate in the GRASP Registry?

A: Patients contact the site investigator to discuss the GRASP Registry and review the necessary documents and forms. Once a patient signs the consent they are enrolled into the GRASP Registry.

Q: What activities do participants complete for the GRASP Registry?

A: Participants should complete assessments and required therapy.

Q: What kind of assessments need to be completed?

A: Participants will be given the Wolf Motor Function Test and the Fugl-Meyer Test by a trained therapist. Throughout the GRASP Registry, participants will also be surveyed about topics such as quality of life and activities of daily living.

Q: When is the Baseline visit?

A: Baseline is after enrollment but before implant.

Q: What are the timepoints for the GRASP Registry?

A: Data will be collected at baseline, 3, 6, and 12 months after implantation, and then yearly thereafter for up to 3 years post-implant.

Q: Is the GRASP Registry information secure?

A: Yes, all information is stored in a HIPAA-compliant electronic database system.

Q: What if a potential participant has concerns with the consent?

A: There is no obligation to join the GRASP Registry. The site's coordinator or investigator can discuss the patient's concerns. If the patient does not agree with the consent form, then they should not consent.

Q: Can a participant leave the GRASP Registry after it has begun?

A: Yes, they can withdraw their consent at any time.

Q: Where can I learn more information about the GRASP Registry?

A: <https://clinicaltrials.gov/ct2/show/NCT05301140>

GRASP Registry Site Contact Information

Surgeon: Dr. Neil Haranhalli , White Plains Hospital	Registry Primary Investigatory: Dr. Jaskarian Ghuman Burke Rehabilitation Hospital
Coordinator: Danielle Toohey, OT RL, Research Therapist	Phone: 914-597-2853
Study Mgr: Josette Hartnett, MPH, Sr. Mgr. Clinical Research	Phone: 914-597-2367



Learn more by contacting a Vivistim representative or by visiting Vivistim.com



info@vivistim.com
(855) 628-9375

The Vivistim® Paired VNS™ System (Vivistim) is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. Do not use if you have had a bilateral or left cervical vagotomy. Risks may include, but are not limited to, pain after surgery, hoarseness, bruising, swelling, coughing and throat irritation. While not observed with Vivistim, infection is a risk associated with surgery. Rx only. For full safety information, please see vivistim.com/safety.