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CLINICAL TRIAL ANNOUNCEMENT

A Randomized Study Assessing Vagus Nerve Stimulation (VNS) for Improved Upper Limb Motor Function After Stroke

Official Title: A Pivotal Randomized Study Assessing Vagus Nerve Stimulation (VNS) During Rehabilitation for Improved Upper Limb Motor Function After Stroke (VNS-REHAB)

Despite the explosion of rehabilitation-related research being conducted in patients post-stroke, there has not yet been a reduction in the disability after stroke. Although overarching neuroplasticity principles have had a great influence, it may be that additional facilitation of neuroplastic change is required. Pairing rehabilitation with release of neuromodulators via indirect activation of the nucleus basalis (NB) and locus ceruleus (LC) neurons, releases acetylcholine and norepinephrine into the cortex. This enhances neural plasticity which is what may be what is required for true meaningful change in people with stroke.

This is a pivotal phase study where subjects are surgically implanted with the Vivistim System consisting of a neurostimulator, lead and electrode, and an external controller. The patient is then randomized to either study treatment or active-control treatment. The study is intended to provide evidence that VNS paired with rehabilitation, in subjects suffering from upper extremity paresis after stroke, is a safe and effective treatment for recovery of upper limb motor function after stroke.

This study has three distinct stages: Stage I, an acute blinded stage, Stage II, an unblinded stage through one year of standard VNS, and Stage III, an unblinded stage for yearly follow-up after one year of VNS. The Control group crosses over to VNS treatment at Stage II.

Key Inclusion Criteria:

- History of unilateral supratentorial ischemic stroke that occurred at least 9 months but not more than 10 years prior to consent.
- Age >22 years and <80 years.
- Fugl-Meyer Arm - Upper Extremity (FMA-UE) score of 20 to 50.