

Long-Term, Observational, Multi-Center Patient Outcome Registry to Collect Data in Patients with Treatment Resistant Depression (TRD) – PI: Prashant Gajwani, M.D.

Vagus Nerve Stimulation (VNS) is an electrical stimulation therapy that shows to be a promising new method for treating patients with severe treatment-resistant depression. VNS treatment involves stimulating the left vagus nerve in the neck with a series of miniscule electrical pulses traveling through a small surgically implanted wire attached to a pulse generator in the chest. The pulse generator delivers stimulation to the vagus nerve in individualized therapeutic "doses."

Dr. Prashant Gajwani is spear-heading efforts to create a registry of data on patients with "treatment-resistant depression". A registry is a collection of information from a set group of patients. No particular treatment is required. Participants will allow Dr. Gajwani to follow the progress of their care. There will be two groups of patients with treatment resistant depression who will be asked to participate in this registry. One group will be patients who have decided with their doctor to have Cyberonics' Vagus Nerve Stimulation (VNS) Therapy™ System for their treatment. The other group will not be treated with VNS. The VNS group will be followed for five (5) years. The non-VNS group will be followed for 2 or 5 years. This registry will collect information about responses to treatments; quality of life; productivity; and use of healthcare services; from patients with treatment-resistant depression. Each group will have 1,000 participants from across the country, for a total of 2,000 in the registry. Participants will continue to receive regular treatment from their doctor during this registry.