

Humanitarian Use Device: Medtronic DBS Therapy for Dystonia (HDE #H020007)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 7 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 7 to 99 years old - diagnosed with chronic, intractable (drug refractory) primary dystonia determined by a neurologist or neurosurgeon

Exclusion Criteria:

- patients who are at significant surgical risk as determined by the neurosurgeon and/or anesthesiologist - patients who have not had an adequate trial of medical or non-surgical treatment

Conditions & Interventions

Conditions:

Brain & Nervous System

Keywords:

DBS, Deep Brain Stimulation, Dystonia

More Information

Description: Humanitarian use devices are medical devices approved by the FDA for the treatment of medical conditions affecting fewer than 4,000 patients per year. The FDA reviewed the safety of the device and determined that the probable health benefits outweigh the risks of injury or illness from its use. Effective treatment of symptoms, however, has not been studied in formal clinical trials. Medtronic DBS Therapy delivers electrical stimulation to areas in the brain to help control symptoms of various movement disorders. You may be a candidate for Medtronic DBS Therapy for Dystonia if you have been diagnosed with chronic, intractable (drug refractory) primary dystonia. You or your third party payer (health insurance, Medicare, Medicaid or other) must provide payment for hospital, office and other medical costs related to this therapy.

Study Contact: Kelly Ryberg - rybe0010@umn.edu

Principal Investigator: Jerrold Vitek

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