

Research Study Recruiting Volunteers

Deep Brain Stimulation for Spasmodic Dysphonia / Laryngeal dystonia

Researchers at the Indiana University, Departments of Otolaryngology Head and Neck Surgery, Neurosurgery, Neurology, and Speech, Language and Hearing Sciences are conducting research studying the usefulness of deep brain stimulation for treatment of adductor spasmodic dysphonia. The goal of this research is to study the vocal fold movement patterns of voice disorder and overall voice quality, before, during, and after deep brain stimulation surgery. Information from this study will help us better evaluate and treat patients with adductor spasmodic dysphonia.

The study will require multiple visits. Study participants will receive compensation for participating in the study. The study will take place at the IU Health Methodist Hospital in Indianapolis, Indiana.

What is laryngeal dystonia?

Laryngeal dystonia is an abnormal movement of the vocal cords (larynx) that results in difficulty with voice production. You may be experiencing uncontrolled voice breaks due to forceful closure of the vocal folds (adductor spasmodic dysphonia / adductor laryngeal dystonia) or forceful opening of the vocal folds (abductor spasmodic dysphonia / abductor laryngeal dystonia). Patients typically undergo botox injections to the vocal folds to treat the symptoms of this disorder. Some patients continue to experience voice problems despite best current treatments. We are currently investigating the role of brain surgery called the 'deep brain stimulation (DBS),' in treating the symptoms of *adductor* laryngeal dystonia.

What is DBS?

Deep brain stimulation is a surgical procedure used routinely to treat various neurological disorders. It is in established clinical use for dystonia. It involves placement of permanent stimulating electrodes into the brain by a neurosurgeon. The placement of electrodes in the brain can involve different areas of the brain depending on the type of dystonia. For the study the electrodes will be implanted in the brain area called the Globus Pallidus Internus (GPi). After surgery, the DBS system is programmed by the neurologist between 2-4 weeks after DBS surgery, to provide clinical effect. Stable clinically effective DBS settings are typically achieved in 4-6 months, with 3-4 visits after surgery.

How is DBS surgery scheduled?

Surgery is done in 2 separate stages, separated by approximately 14-21 days.

Stage 1 – surgery with overnight stay in hospital (insertion of brain electrodes)

Stage 2 – surgery is an outpatient procedure (brain electrodes are connected to a extension leads and generator)

What does the study involve?

The aim of the study is to determine how effective DBS is in treating adductor laryngeal dystonia. As part of the study, you will undergo audio voice recordings, endoscopic imaging to view the vocal folds, MRI of the brain, complete neurological evaluation, and neuropsychological evaluation before surgery. If you are enrolled, you will then undergo DBS implantation. During DBS surgery we will conduct audio recordings and imaging of the voice box. After surgery, we will determine the effect of DBS on your voice and function with audio voice recordings, video imaging of your larynx, neuropsychological testing, and MRI scanning of your brain at 6 months following the DBS surgery.

You may qualify for the study if you:

- Are between 18-70 years of age
- Have a diagnosis of adductor spasmodic dysphonia or adductor spasmodic dysphonia plus tremor
- Are a native speaker of American English
- Are right-handed
- Have no evidence of dementia or any severe untreated mood / neurological disorder
- Are at least 3 months since your last botulinum toxin injection to the vocal folds
- Are not pregnant or currently breastfeeding
- Do not have ferromagnetic implants in your body, e.g. cardiac implants

For more information, please contact:

Rita R. Patel

812-855-3886

patelrir@iu.edu