Abbott

ADROIT

Abbott DBS Registry of Outcomes for Indications over Time

Study Summary

Principal Investigator: Sean Nagel, MD
Site: Cleveland Clinic

Information for patients receiving DBS for Parkinson's disease, essential tremor, or dystonia:

What is the purpose of the study? Your doctor has recommended that you receive Deep Brain Stimulation (DBS). Abbott, the manufacturer of the DBS device, would like to collect data and outcomes on DBS systems to have information on how they perform over time.

How will it be done? There are nine study visits, which are the time points when many DBS patients go to see their doctor. Information about your DBS system will be recorded at the following points:

- The **Baseline** visit, to collect information about you and your medical condition. Your doctor will evaluate your movement using the following questionnaires: UPDRS and Hoehn and Yahr (for Parkinson's disease), the Fahn-Tolosa-Marin Tremor Rating Scale (FTM-TRS, for essential tremor), or the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS, for dystonia), and the Clinical Global Impression questionnaire for all patients. You will be also asked to complete several questionnaires about how you feel and your activities, including EQ-5D and PDQ-39 that measure quality of life, patient global impression, and any previous hospitalizations. Your doctor may ask to you to complete the Montreal Cognitive Assessment and Beck Depression Inventory. If you have a caregiver who helps to take care of you, that person may also be asked to fill out the caregiver global impression and Zarit Burden Interview.
- The **Implant** visit, to collect information about your DBS implant.
- The **Initial Programming** visit, when your DBS device is turned on and programmed.
- **Follow-up visits** at 6 months, 1 year, 2 years, 3 years, 4 years, and 5 years after your DBS device is turned on. At follow-up visits, you and your caregiver will be asked to complete the same questionnaires you completed at the baseline visit. You will also be asked to report any complications, and your DBS device settings may be modified if necessary.

If anything goes wrong with your DBS system or if you go to the hospital, it will be recorded.

Is there an additional benefit for you? The activities in this study are part of your routine care. Your insurance will be billed as usual. There won't be any direct benefit for you from taking part in this research. The information about your experience with DBS could help the future development of this treatment.

Why would someone decide NOT to participate in this study? This is a study to collect data on DBS devices that are approved and used on doctor's orders. None of the procedures in this study are experimental. You will receive the same implant even if you don't take part in the study. It may take longer to complete your study visits. The information should be collected in about an hour, but the baseline visit could take longer. The study does not collect any information that could identify you, but there is a small risk of loss of confidentiality when the information is collected from you and your caregiver.

For more information, please contact:

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