Atlas Predicted DBS settings in Essential tremor, ID# 160155

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Overview:

Essential tremor is a chronic progressive condition that results in disability and decreasing quality of life. Deep Brain Stimulation of the ventral intermediate nucleus of the thalamus has been shown to improve tremor of the limb up to 90% and was FDA approved in 1997.

One of the challenges of programming is the time it takes to optimize the tremor control. The initial clinic visits can take some time and may require additional visits to further optimize. This can be a significant burden on the patient due to lost productivity, disability and financial impacts.

Programming DBS entails evaluating the degree of tremor control at each contact, of which there are four on each lead and asses for side effects. This data allows the neurologist to choose the nest contact to stimulate from. This process can be tedious and is hampered by variability in the tremor frequency and amplitude that is inherent in ET, but also that there is often lingering benefit from the placement of the electrode is surgery. This benefit arises from the swelling that occurs with the multiple electrodes that are passed into the brain in order to determine the optimal placement, this effect does resolve.

Current DBS technology allows only for 4 contacts on each lead, currently in development with multiple companies are 8 to 16 contact leads and leads that allow for the current to be directed away from areas of side effects and toward the area of best efficacy. This will allow for better patient outcomes, however programming these leads with our current standard of care is daunting and would be too time consuming to be done practically in a standard DBS programming session. An alternative method would need to be found.

In order to facilitate safer and more effective lead placement in the operating room a functional atlas was created. This atlas is based on both the side effects and efficacy of symptom control data that is obtained in the OR and then plotted in reference to known points on the patient's pre-operative MRI. This atlas has allowed for faster and safer surgical planning for our DBS patients. We would like to use this atlas to predict the optimal contact and settings to program the DBS to, allowing a faster response to programing.

Methods:

Patients who have been approved for DBS of the VIM nucleus of the thalamus to treat essential tremor will be approached to participate in the study. They will undergo our standard of care DBS electrode implantation. 30 patients will be studied after they sign the consent form. They may exit the study at any time.

On the day of their initial programming, which takes place in one of two locations the Vanderbilt Neurosurgery clinic or the Vanderbilt Neurology clinic, the patient will undergo the standard of care post-op CT scan of the brain to establish the final lead position. They will then undergo the standard evaluation of the DBS electrode to determine the optimal contact and settings to control their tremor. This will be done on both side if the patient has undergone a bilateral implant.

At the same time another neurologist will evaluate the DBS lead placement within the Vanderbilt functional atlas. They will determine the ideal contact to stimulate from as well as he predicted DBS settings including voltage and pulse width.

Once the two contacts have been determined they will be programmed into the patient system by the unblended neurologist. In a random fashion the two programs will be labeled either group A or B. The patient will also be blinded to the nature of the programs. This should take about 20 minutes longer than our standard initial programming session of an hour.

For the first two weeks patients will use group A and then after 2 weeks they will change to group B. At the end of the first two weeks the patient will fill out the ADL section of the FTM (Fahn-Tolusa-Marsden tremor rating scale) to rate their tremor control over the past two weeks. The compliance with this will be noted by the percentage of use of each group.

After one month the patient will return to clinic to undergo a formal evaluation of both tremor settings. This evaluation will include formal tremor rating scales using the FTM. These ratings will be video recorded. These evaluations will be performed by a blinded neurologist. Once group B has been evaluated they will change back to group A and wait 1 hour to allow for optimal tremor control to occur.

At the end of the session the patient will choose which program they liked the best and will be allowed additional programming to improve their tremor control. This should take about 3 hours.

At any point during the study period the patient may opt out if they are unhappy with their tremor control, they will exit the study and opt to choose the group they like the best and can be seen in clinic for additional programming.

Analysis:

The primary outcome measure is the difference on the FTM scale per side, each side will evaluated with the following items of the FTM to allow limb specific response:

Items: 5, 6, 11 and 14, these will be compared with a t-test

The total FTM will also be compared with the t-test as a secondary outcome

If there are any adverse events or unanticipated risks occur they will first be reported to the PI and to the IRB if they are deemed as SAE or unexpected. The protocol will then be re-assessed and changed in order to avoid further events and to ensure patient safety.

All subject related data will be kept on a password protected computer and will be kept for at least 6 years after the study closes.