IpsiHand Device Use in Stroke Patients to Assess Functional Motor Outcomes

ClinicalTrials.gov Identifier: NCT04338971

Study Protocol

The study is a prospective, non randomized, self controlled study performed in two phases across two investigational sites. The study protocol allowed for a total completion of up to 20 adult subjects (18-85 years of age) who is a chronic stroke survivor of 6 months or more post stroke. Subject must have residual hemiparesis in the upper extremity.

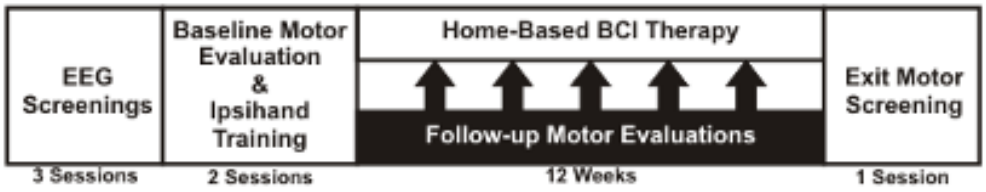
To be included in this study, subjects completed screening assessments to ensure subjects had intact cognition to follow directions, intact vision without visual-spatial neglect, and motor screening to ensure no contractures were present, to ensure the device would fit safely and comfortably. If criteria was met, subjects would progress to *Phase 1*.

Phase 1 required subjects to complete EEG screenings to ensure an EEG signal was present and adequate to control the opening and closing of the robotic hand exoskeleton. Should an adequate EEG signal be present, subjects would progress to *Phase 2*.

Phase 2, A clinical specialist completed baseline motor evaluations were completed, and each subject received skilled training with an IpsiHand Handpiece. The primary outcome measure used in this study was the Fugl-Meyer Assessment - Upper Extremity. The clinical specialist provided full training and skilled education regarding the set-up, management, and use of the Neurolutions IpsiHand System for home therapy. The Clinical Specialist educated each subject concerning how to use the EEG signals to control the IpsiHand Handpiece, and how to clean and store the device when not in use. Each subject was given the opportunity to ask questions.

Each subject was instructed to use the Neurolutions IpsiHand System at home daily, for a use target of one session, five (5) out of seven (7) consecutive days per week for a total of 12 weeks. On each day of IpsiHand Therapy, the subjects completed up to five (5) 10-minute runs of the cued task per day. Each 10-minute run of the cued task consisted of 30 trials in which subjects tried to open the exoskeleton by performing motor imagery and 30 trials, targeting to achieve a minimum of 150 repetitions per day. **Figure 1** shows the sequence of timepoints.

Figure 1: Study Timeline



Motor evaluations occurred by clinical specialists specifically trained to administer the Fugl-Meyer Assessment - Upper Extremity. These motor evaluations occurred before receiving IpsiHand training (Baseline), 4-week, 8-week and 12-week timepoints. The primary measure of statistical success was the Fugl-Meyer. The Fugl-Meyer Assessment of the Upper Extremity was used to assess the impact of the device in improving upper limb motor function and served as the primary measure of statistical success, as determined by using a two-sided one-sample t-test, assuming a normal distribution of scores. The Fugl-Meyer Assessment of the Upper Extremity was selected as the primary measure of statistical success based on FDA guidance and increased sensitivity of t1he measure, with a reduced floor effect as compared to the Action Research Arm Test (ARAT).

Statistical Methods

This study tested whether the Neurolutions System provides rehabilitative benefits for stroke survivors. The central hypotheses are that ipsilateral motor signals from the unaffected hemisphere in chronic stroke survivors can be used to control a BCI system and furthermore, that use of the Neurolutions IpsiHand System will enhance functional recovery through endogenous plasticity
A two-sided, one-sample t-test, examining the change in motor function from baseline to study completion, was used to evaluate the statistical significance (alpha = 0.05) of UEFM changes.

In addition to statistical analysis, the data was evaluated for clinical significance by utilizing established Minimal Clinically Important Difference (MCID) scores for the UEFM. The MCID has been defined as an increase of 5.25 points from baseline in those with minimum to moderate hemiparesis in the chronic phase (>=6 months) of stroke.

Study Sites

The study locations were St. Louis, MO and Santa Cruz, CA.

Principal Investigator

The principal investigator was Alexandre Carter, MD, PhD.