Providing Brain Control of Extracorporeal Devices to Patients With Quadriplegia

Protocol Number: HS-12-00476

National Clinical Trial (NCT) Identified Number: NCT01849822

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13.0 Statistical Considerations

13.1 Study Objectives

This feasibility study is designed to evaluate the safety and effectiveness of the NPS, a device which records brain activity from the posterior parietal cortex. The safety of the device will be evaluated by monitoring the health of the implant over the course of the study. The effectiveness of the device will be evaluated by monitoring accuracy in certain tasks, as the subjects attempt use their thoughts to control external effectors, and by monitoring the subjects' quality of life, as measured by the quality-of-life index (QOLI) throughout the study. Two subjects will be enrolled in this study. Each subject will serve as his or her own control.

13.2 Accrual

The expected accrual rate for this study is 0.06% (two subjects enrolled out of a population of approximately 3,000 patients seen regularly at RLANRC with some degree of paralysis). The accrual goal is two. Only one site, RLANRC, will be involved in recruiting subjects for this study.

13.3 Study Design

This study is designed as a longitudinal feasibility study in which two subjects will each receive the NPS and each will serve as his or her own control. Each subject may withdraw from the study independently of the other before reaching the end of the study period at his or her request, physician request, or due to an adverse event. If an adverse event occurs which is determined to be caused by a defect of the device, which is determined to place undue risk on the subjects of the study, the study will end early and all enrolled subjects will be withdrawn from the study.

No stratification factors will be incorporated into this study. Both study subjects will be recruited from the same population of paralyzed patients with history of high cervical spinal lesion (C4 and above), and other inclusion and exclusion criteria as outlined in the inclusion criteria (Section 5.0).

13.4 Statistical Power of the Study

With only two subjects, the statistical power of this study to support conclusions for the population of paralyzed patients at large is weak. This study is not intended to bring statistical power to bear on making conclusions about the absolute safety of the device. This is a pilot study intended to evaluate the basic safety and effectiveness of the device. Given the nature of the device and its early state of development, it is appropriate and necessary to initiate a small, longitudinal feasibility study. Therefore, only two subjects will be recruited into the study. The study outcomes for these subjects will be used to evaluate whether more and larger studies are warranted.

13.5 Power to Address Objectives

The primary objective of this study is to evaluate the safety of the NPS. By implanting the device in two subjects and monitoring their health over the course of the study, the primary safety objective will be satisfied.

The secondary objective of this study is to evaluate the effectiveness of the NPS when controlling virtual or physical end effectors. By monitoring the subjects as they perform study tasks using the NPS, the primary effectiveness objectives of this study will be satisfied.