THE BIGIDEA

Pre-Screening & Screening (Months #1-2)

- Potential candidates identified by Victory over Paralysis research database
- If potentially eligible and interested, candidate is consented for screening and further assessed for eligibility to participate in the study and further assessed for study eligibility

Usual Care (Months #3-5)

- Candidate continues on with his/her current daily activities
- At the conclusion of Usual Care, candidate is enrolled in the study and randomized into group A or group B

Pre-Implant Assessments (Month #6)

• Participant returns to Louisville to complete pre-implant assessments

Implant Surgery (Month #7)

Pre-Intervention Assessments (Month #8)

Participants (N = 36) are randomized into one of six treatment interventions (A1, A2, A3; B1, B2, B3).

Group A - no weight-bearing standing with each treatment intervention; each intervention has one of the three different stimulation types (voluntary movement, cardiovascular, standing).

Group B – weight-bearing standing with each treatment intervention; each intervention has three different stimulation types (voluntary movement, cardiovascular, standing).

Intervention #1 (Months #9-13)

• During these months, subject participates in his/her assigned cohort intervention (approximately 80 sessions, two hours/session)

Post-Intervention #1 Assessments (Month #14)

Intervention #2 (Months #15-19)

• During these months, subject participates in his/her assigned cohort intervention (approximately 80 sessions, two hours/session)

Post-Intervention #2 Assessments (Month #20)

Home & Community Follow-up (Months #21-23)

- Participant can opt to keep the epidural stimulator or have it removed
- Follow-up studies at 6 and 12 months

Follow-Up (Month #24 and ongoing)

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