



**JOHN WAYNE
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CLINICAL TRIAL ANNOUNCEMENT

Study of Modified Stem Cells (SB623) in Patients with Chronic Motor Deficit from Traumatic Brain Injury

Official Title: A Double-Blind, Controlled Phase 2 Study of the Safety and Efficacy of Modified Stem Cells (SB623) in Patients with Chronic Motor Deficit from Traumatic Brain Injury (TBI)

This is a double-blind, sham-surgery controlled study of stereotactic, intracranial injection of SB623 cells in patients with fixed motor deficits from traumatic brain injury.

Two groups, Group 1 (2.5, 5, and 10 million SB623 cells combined) and Group 2 (sham placebo), will be included in this study in a 3:1 randomization scheme. Group 1 will be further randomized in a 1:1:1 ratio to receive either 2.5 million SB623 cells, 5 million SB623 cells, or 10 million SB623 cells. Group 2 will receive a sham surgery at a 3:1 randomization ratio. Randomization will be performed via an interactive web/voice response system (IXRS), stratified by GOS-E score (recorded in the IXRS at the clinical site).

SB623 cells are bone-marrow-derived stromal cells that have been transiently transfected with the intercellular domain of the human Notch-1 gene.

Key Inclusion Criteria:

- Age 18-75 years
- Documented history of TBI, with correlated findings by MRI or CT
- At least 12 months post-TBI
- GOS-E score of 3-6 (i.e. moderate or severe disability)

Key Exclusion Criteria:

- History or presence of any other major neurological disease
- Any seizures in the prior 3 months
- Presence of craniectomy (without bone flap replacement) or other contraindication to stereotactic surgery