JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

Study of Modified Stem Cells (SB623) in Patients With Chronic Motor Deficit From Ischemic Stroke

Official Title: A Double-Blind, Controlled Phase 2b Study of the Safety and Efficacy of Modified Stem Cells (SB623) in Patients With Chronic Motor Deficit From Ischemic Stroke

This is a double-blind, sham-surgery controlled study of stereotactic, intracranial injection of SB623 cells in patients with fixed motor deficits from ischemic stroke. The study will be conducted at approximately 65 sites in the United States.

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 completed ischemic stroke in subcortical region of MCA or lenticulostriate artery with or without cortical involvement
- Between 6 and 90 months (7.5 years) post-stroke, and having a chronic motor neurological deficit
- Neurological motor deficit substantially due to incident stroke
- Modified Rankin Score of 2-4
- Require Motricity Index 30-75 (UE Scale) or 27-74 (LE Scale)
- Able to undergo all planned neurological assessments
- Able and willing to undergo magneti resonance imaging (MRI) with contrast and computed tomography (CT)
- Agree that use of antiplatelet, anti-coagulant, or non-steroidal anti-inflammatory drugs to be determined by the local medical staff and in accordance with the ACCP 2012 guideline "Perioperative Management of Antithrombotic Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th Edition: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines"
- Subjects must have had physical therapy prior to entry (and be willing to continue to the extent possible)
- Must be willing to discontinue herbal or non-traditional medicines for 1 week before and 1 week after the surgical procedure and be willing to continue to the extent possible
- Ability of patient or legal authorized representative to understand and sign an Informed Consent

For more information, please contact the Neuro-Oncology Clinical Trial Team at:
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