Proposed Stroke Recovery Pilot Clinical Study Protocol

Bioelectrical Stimulation and Micro Infusion Pump Delivery Stem Cell Based Composition for Treating Ischemic Stroke (BMIPS)

Study Details & Description

Field	Details
Condition or Disease	Stroke
Intervention/treatment	Device: Deep Brain Stimulation (DBS) targeting signals – SCP1, SCP2, SCP3, SCP4, SCP5 Biologic: CC-15 Cell Preparation Cocktail composed of stem cells, growth factors, exosomes, micro RNAs, amino acids, PBS, selected nutrients including neurotransmitters, nutrients engineered hydrogel and brain matrix, growth factor supplements include IGF-1, FGF, BDNF and GDNF

Detailed Description

The proposed study is a safety and feasibility study intended to provide preliminary data to design a future pivotal study. The objective of this study is to determine the safety and feasibility of electrical stimulation combined with micro infusion delivery of stem cell based composition in patients with ischemic stroke.

Study Design

Field	Details
Study Type	Interventional (Clinical Trial)

Estimated Enrollment	12 participants
Intervention Model	Single Group Assignment
Masking	None (Open Label)
Primary Purpose	Treatment
Official Title	Bioelectrical Stimulation and Micro Infusion Pump Delivery of Stem Cell Based Composition for Treating Ischemic Stroke: A Safety and Feasibility Study
Study Start Date	June 2018
Estimated Primary Completion Date	January 2019
Estimated Study Completion Date	July 2019

Arms and Interventions

Arm	Intervention/treatment
Experimental: Electrical Stimulation	This is a single arm study and all subjects will receive electrical stimulation and micro infusion pump delivery of the CC-15 Stem Cell Based Composition. Device: Deep Brain Stimulation Electrical stimulation of dentate nucleus area of the cerebellum Device: Microinfusion Pump Biologic: CC-15 Stem Cell Growth Factor Based Cocktail

Outcome Measures

Primary Outcome Measures:	Adverse Events (Time Frame: 6 months) Incidence of serious adverse events

Eligibility Criteria

Information from the National Library of Medicine
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study.

Field	Details
Ages Eligible for Study	35 Years to 75 Years (Adult, Senior)
Sexes Eligible for Study	All
Accepts Healthy Volunteers	No

Criteria

Key Inclusion Criteria:

- One-time stroke that occurred 1–3 years ago (i.e., not acute; 3–36 months)
- Stroke due to either blood vessel occlusion or hemorrhagic stroke
- Moderate stroke weakness more than 6 months (unilateral upper extremity hemiparesis)

Key Exclusion Criteria:

- Seizures since time of stroke (i.e., seizures or seizure disorder)
- Unable to have MRI (i.e., contraindication for MRI)

Contacts and Locations

Contact: Dr. Leslie Miller, Chief Medical Officer email lmiller@secondheartinc.com

Locations
United States
TBD

Sponsors and Collaborators
CerebraCell a Leonhardt's Launchpad co.
Investigators
Principal Investigator: TBD

More Information

Field	Details
Responsible Party	CerebraCell Laboratories
ClinicalTrials.gov Identifier	N/A
First Posted	March 21, 2018
Last Update Posted	March 21, 2018
Last Verified	March 2018
Individual Participant Data (IPD) Sharing Statement	No

Keywords provided by CerebraCell Laboratories

Ischemic Stroke	Physical Therapy
Deep Brain Stimulation	Rehab
DBS	Brain Stimulation

Additional relevant MeSH terms

Stroke	Nervous System Diseases
Paresis	Vascular Diseases
Cerebrovascular Disorders	Cardiovascular Diseases
Brain Diseases	Neurodegenerative Diseases
Central Nervous System Diseases	Soft Tissue Injuries