
A Phase 3, Randomized, Placebo-controlled Multicenter Study to Evaluate Efficacy & Safety of Repeated Administrations of NurOwn® in Patients with ALS

Grant Award Details

A Phase 3, Randomized, Placebo-controlled Multicenter Study to Evaluate Efficacy & Safety of Repeated Administrations of NurOwn® in Patients with ALS

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-09894

Project Objective: Complete a Phase 3, Randomized, Placebo-controlled Multicenter Study to Evaluate Efficacy & Safety of Repeated Administrations of NurOwn® in Patients with ALS

Investigator:

| | |
|---------------------|------------------------------|
| Name: | Ralph Kern |
| Institution: | BrainStorm Cell Therapeutics |
| Type: | PI |

Disease Focus: Amyotrophic Lateral Sclerosis, Neurological Disorders

Human Stem Cell Use: Adult Stem Cell

Award Value: \$15,912,390

Status: Active

Grant Application Details

Application Title: A Phase 3, Randomized, Placebo-controlled Multicenter Study to Evaluate Efficacy & Safety of Repeated Administrations of NurOwn® in Patients with ALS

Public Abstract: **Therapeutic Candidate or Device**

A cell therapy that delivers high levels of neurotrophic factors to the CNS

Indication

Amyotrophic lateral sclerosis (ALS) or Lou Gehrig Disease

Therapeutic Mechanism

The Cell therapy is aimed at providing high levels of neurotrophic factors directly to the CNS, to support the dying neurons

Unmet Medical Need

Amyotrophic lateral sclerosis (ALS) is a fatal neurological disease in which the degeneration and death of motor neurons (MNs) leads to weakness, paralysis and eventually respiratory failure . There remains a great unmet medical need for safe and effective treatments for people with ALS.

Project Objective

Phase 3 completed

Major Proposed Activities

- Manufacturing of cell therapy product
- Enrolling 200 patients for the study
- Run clinical trial

Statement of Benefit to California: Manufacturing of the cell therapy product for all US medical centers participating in the study will be exclusively in California
The study will include 2 clinical sites in California that will enroll 80 Californian patients of the the total 200 patients in the study.

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