

A Single-Blind, Randomized, Parallel Arm, Phase II Proof-of-Concept Study of the Safety and Efficacy of HuCNS-SC Transplantation in Cervical Spinal Cord Injury

UPMC Rehabilitation Institute is pleased to announce we are approved for participation in a new randomized clinical trial involving cervical spinal cord injured persons. We have been selected as one of fourteen proposed sites to enroll and follow study participants in this groundbreaking clinical trial.

This study is being done to determine whether an investigational product called human central nervous system stem cells (HuCNS-SC) may benefit people with a traumatic C5-C7 cervical spinal cord injury, classified by the American Spinal Injury Association ASIA Impairment Scale (AIS) as an AIS Grade A or B injury. The study will evaluate whether the investigational product is safe in these people following transplantation of the cells.

Participants enrolled in this study will undergo an experimental surgical procedure in which HuCNS-SC cells will be injected into the spinal cord. Six patients will receive stem cells in an open label design. Afterwards, the next 40 participants will be randomized to stem cells or will serve as control subjects, and will not undergo study surgery or receive the investigational product. All participants in the study (regardless of whether they have surgery) will be followed for approximately one year.

Participants must be between ages 18 – 60 years old and have had a traumatic spinal cord injury. They must be at least 16 weeks to 1 to 2 years post injury date depending on AIS level.

I you believe you have a patient who maybe be eligible for this clinical trial please contact:

Michael Munin MD
Primary Investigator
UPMC Dept. PMR
3471 Fifth Ave. Kaufmann 201
Pittsburgh, PA 15213
412-648-6848 office
412-692-4410 fax
muninmc@upmc.edu

Karen Greenwald RN BSN CCRC Study Coordinator UPMC Dept. PMR 3471 Fifth Ave. Kaufmann 201 Pittsburgh, PA 15213 412-692-2084 office 412-692-4410 fax greekk@upmc.edu