Clinical study to evaluate safety of investigational cell therapy to treat chronic motor deficits after stroke

Published on April 27, 2016 at 3:49 PM

University Hospitals Case Medical Center is the first surgical site for a Phase 2b clinical trial study to further evaluate the safety and efficacy of an investigational cell therapy for the treatment of chronic motor deficit following an ischemic stroke.

"With strokes, focus has been on prevention or treatment within the first few hours," said Jonathan Miller, MD, Director of the Center for Functional and Restorative Neurosurgery at UH Case Medical Center and Assistant Professor of Neurosurgery at Case Western Reserve University School of Medicine, who performs the stem cell surgery as part of the study. "Stroke is the leading cause of adult disability in the U.S., and there really hasn't been much for this patient population."

Ischemic strokes account for approximately 87 percent of all strokes in the US and occur when there is an obstruction in a blood vessel supplying oxygen to the brain. With approximately 800,000 strokes occurring in the United States every year, stroke is the leading cause of acquired disability in the United States. Traditional stroke treatments generally show little or no improvement in patients after the first six months following a stroke.

The ACTIsSIMA "Allogeneic Cell Therapy for Ischemic Stroke to Improve Motor Abilities" trial will examine the effects of genetically modified adult bone-marrow-derived stem cells in patients who have experienced an ischemic stroke in the previous six months to five years and still suffer from motor impairments.

Dr. Miller said, "For the hundreds of thousands of people living with the debilitating effects of ischemic stroke, the ACTIsSIMA trial will help determine whether this investigational cell therapy is a safe and effective treatment option."

The Phase 2b clinical trial follows a previous open label Phase 1/2a clinical trial in a similar patient population. The Phase 2b study will further evaluate the safety and efficacy of the treatment in a blinded and controlled setting.

The study will enroll 156 patients with chronic motor deficits after stroke. They are being recruited through 50 assessment sites throughout the United States. Patients will range in age from 18 to 75 years of age. Once enrolled through an assessment site, patients will come to one of 18 surgical sites such as UH Case Medical Center, for the injection of cells. The patient will then be monitored for the duration of the study at the assessment sites. The closest assessment sites to UH are in Toledo and Detroit.

The ACTIsSIMA trial will further evaluate the safety and efficacy of intracranial administration of modified adult bone-marrow-derived stem cells when administered to patients with chronic motor deficit secondary to ischemic stroke.

"UH Case Medical Center has been in the forefront of adult stem cell research," said Dr. Miller. "We are excited to be part of this study to evaluate the potential of this treatment for stroke. Although it will take time, this study and others involving stem cells, may lead to new methods of helping patients."

Source:
University Hospitals Case Medical Center
