Study uses new stem cell therapy in patients up to 19 days after stroke

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Dr. Sean Savitz of UTHealth is senior investigator of a new study using stem therapy up to 19 days after stroke. Credit: UTHealth

The first Texas patient has been enrolled by researchers at The University of Texas Health Science Center at Houston (UTHealth) in the country's first double-blind clinical trial studying the safety and efficacy of an innovative stem cell therapy that can be given up to 19 days after an ischemic stroke.

The Phase II study, cleared by the Federal Drug Administration, examines a regenerative therapy developed by Aldagen that uses a

patient's own bone marrow stem cells. The therapy, called ALD-401, consists of stem cells that are identified using Aldagen's proprietary technology to isolate cells that express high levels of an enzyme that serve as a marker of stem cells.

Studies found that these cells enhance recovery after stroke in mice. The cells are administered into the carotid artery.

"This represents a new approach using stem cells for stroke," said Sean Savitz, M.D., senior investigator for the multi-center study and associate professor of neurology at the UTHealth Medical School. "A major question in the field of stem cell research is whether we can extend the time window for administering stem cells. A longer window increases the number of patients that might be helped."

Preclinical research, including research at UTHealth, has suggested that stem cells can promote the repair of the brain after an ischemic stroke, which is caused by a blood clot in the brain. Stroke is a leading cause of disability and the fourth-leading cause of death in the United States, according to 2008 statistics reported by the Centers for Disease Control and Prevention.

The Houston resident received either placebo or ALD-401 on June 8 at Memorial Hermann-Texas Medical Center after suffering a stroke May 23 while on a trip to California. Her stroke was caused by previously undiagnosed atrial fibrillation.

"We were waiting for our taxi at the hotel and I immediately couldn't talk and my husband said my face was drooping," said the 67-year-old cosmetics developer. "We were just three blocks from a major trauma center. I had an angel with me because if it had happened two hours later, I would have been on an airplane."

Once back in Houston, she was referred to Savitz' study by Erin Furr-Stimming, M.D., UTHealth assistant professor of neurology, who treats her for Parkinson's disease.

While she doesn't know whether or not she received the stem cells in the double-blind study, she didn't hesitate to join the trial.

"I did a lot of research on stem cells online. I was very excited when I heard about the trial. I wanted to participate in the research for me, if possible, and for other people behind me," she said.

Savitz and his research team are studying other stem cell therapies for acute stroke, and these must be administered within a few days of the stroke. One of those, a safety and efficacy trial using a patient's own bone marrow stem cells administered intravenously, is funded by the National Institutes of Health. UTHealth researchers in the Department of Pediatric Surgery also are studying the use of stem cells for pediatric traumatic brain injury.

Provided by University of Texas Health Science Center at Houston

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