First US patient in novel stem cell trial for stroke disability enrolled at UTHealth

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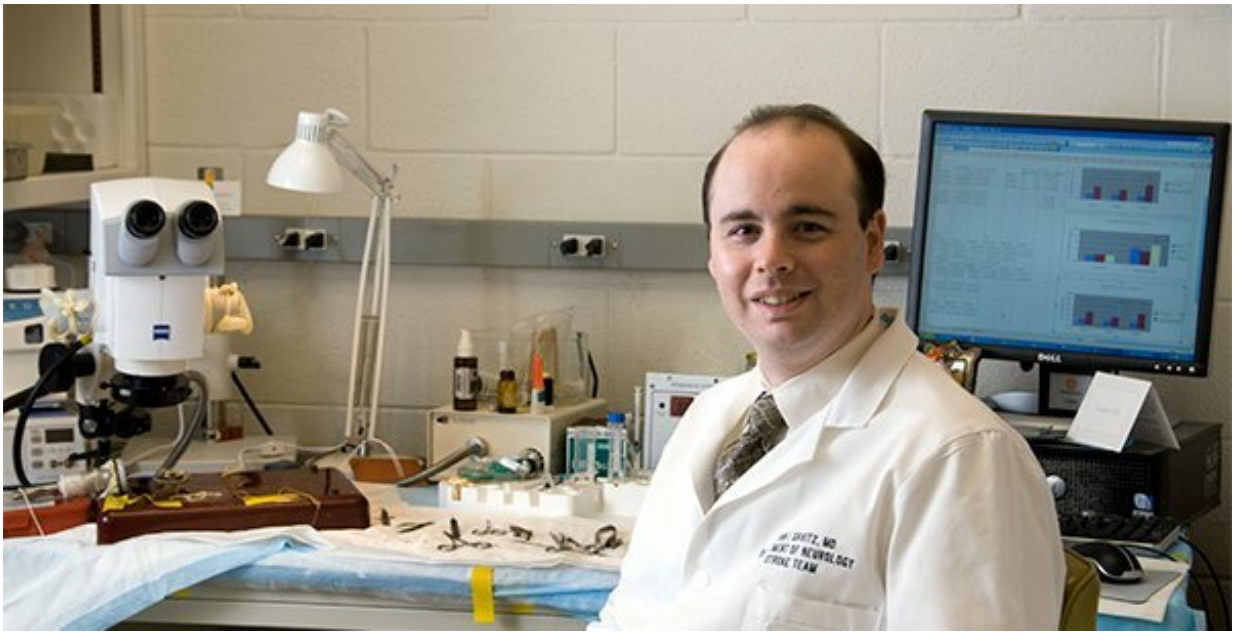

Sean I. Savitz, MD, of McGovern Medical School at UTHealth, has been researching stem cell therapy for stroke for a decade. He is the global principal investigator for a novel therapy study to treat stroke disability. Credit: UTHealth

The first U.S. patient to participate in a global study of a stem cell therapy injected directly into the brain to treat stroke disability was enrolled in the clinical trial this week at The University of Texas Health Science Center at Houston (UTHealth).

"At McGovern Medical School at UTHealth, we have been studying cellular therapies as a novel treatment for stroke over the past 10 years. We are very excited to partner with ReNeuron and enroll the first patient into the PISCES III study," said Sean I. Savitz, MD, the study's global principal investigator and professor and director of the Institute for Stroke and Cerebrovascular Disease at UTHealth. "This study represents an important next step in the development of novel cellular therapies for chronic stroke and, to date, is the most advanced clinical trial to determine whether neural stem cells improve recovery in patients chronically disabled by stroke."

The trial, called PISCES III, is a Phase IIb, randomized, placebo-controlled, multicenter study enrolling a total of 110 eligible ischemic stroke patients, age 35 to 75, who are experiencing persistent disability six to 12 months post-stroke. They will receive either a single dose of the ReNeuron drug called CTX0E03 DP, which is injected into the brain, or they will undergo a sham surgery. The surgeries are performed at Memorial Hermann-Texas Medical Center, a teaching hospital of McGovern Medical School.

While intravenous delivery of stem cells is being studied in clinical trials for acute stroke patients, direct delivery into the brain may have more effect for patients with chronic stroke disability, Savitz said.

"Just as in a skin wound, the brain heals in different stages," said Savitz, professer and Frank M. Yatsu, MD Chair in Neurology at McGovern Medical School. "In animal studies, direct injection in a chronic stroke setting has been shown to improve recovery and outcomes. It appears that the cells are changing the environment of the damaged area of the brain, so it is more pro-regenerative. It may be releasing factors that stimulate the repair mechanism near the area of the infarct." An infarct is a small, localized area of dead tissue resulting from failure of blood supply.

The study brings together an interdisciplinary team that includes Peng R. "Roc" Chen, MD, associate professor in the Vivian L. Smith Department of Neurosurgery; and Monica Verduzco-Gutierrez, MD, associate professor in the Department of Physical Medicine and Rehabilitation at McGovern Medical School. Chen is on the steering committee for the trial and is the surgical lead. Chen brings years of experience to the trial in the surgical administration of stem cells. Verduzco-Gutierrez is the rehabilitation lead who will oversee the assessments of mobility and cognitive function before and after the procedure.

Like Savitz, both faculty members are part of the Institute for Stroke and Cerebrovascular Disease at UTHealth, which was founded in 2017 to use the strength of UTHealth's multidisciplinary experts to advance research and clinical practice in acute stroke treatments, stroke prevention, stroke recovery, population health, and health services.

The intervention arm for PISCES III includes stereotactic surgery, which uses a three-dimensional coordinate system to precisely target the area of the brain to receive the injected therapy through a burr hole. In the placebo arm, patients will receive a tiny, partial burr hole in the skull. All patients will undergo a 12-week physical therapy program. The trial has been approved by the U.S. Food and Drug Administration.

The primary endpoint of the study is a comparison of the proportion of patients in the treated and placebo arms showing a clinically significant improvement on the Modified Rankin Scale, a measure of disability and dependence, at six months post-treatment compared with baseline. Top-line results from the study are expected in early 2020.

Provided by University of Texas Health Science Center at Houston

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