

Safety results of intra-arterial stem cell clinical trial for stroke presented

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Early results of a Phase II intra-arterial stem cell trial for ischemic stroke showed no adverse events associated with the first 10 patients, allowing investigators to expand the study to a targeted total of 100 patients.

The results were presented today by Sean Savitz, M.D., professor of neurology and director of the [Stroke](#) Program at The University of Texas Health Science Center at Houston (UTHealth), at the 8th World Stroke Congress in Brasilia, Brazil.

The trial is the only randomized, double-blind, placebo-controlled intra-arterial clinical trial in the world for [ischemic stroke](#). It is studying the safety and efficacy of a regenerative therapy developed by Aldagen Inc., a wholly-owned subsidiary of Cytomedix, Inc., that uses a patient's own bone marrow stem cells, which can be administered between 13 and 19 days post-stroke.

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 serves as a marker of stem cells. Pre-clinical studies found that these cells enhance recovery after stroke in mice. The cells are administered into the carotid artery. Patients are followed for 12 months to monitor safety and to assess mental and physical function.

"We have been approved by the Data Safety Monitoring Board (DSMB) to move the study into the next phase, which will allow us to expand the number of sites in order to complete enrollment," said Savitz, senior

investigator for the multi-center study. As per the protocol for the trial, the [Food and Drug Administration](#) required a review by the DSMB prior to advancing to the next phase.

Preclinical research, including research at the UTHealth Medical School, 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.

Provided by University of Texas Health Science Center at Houston

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