

Stroke patients show higher recovery in MultiStem therapy

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Data presented by the biotech company Athersys indicate that stroke patients treated by an adult stem cell therapy called MultiStem did significantly better than others who received a placebo one year after treatment. The results are from a Phase 2 study involving clinical sites in the United States and the United Kingdom, including University Hospitals Case Medical Center. The study examined the safety and effectiveness of the new therapy developed for the treatment of ischemic stroke. The data were presented Feb. 17 at the 2016 International Stroke Conference in Los Angeles.

Of the 65 <u>patients</u> treated with MultiStem, 23.1 percent achieved a complete or near full recovery from their <u>stroke</u> after one year. Only 8.2 percent of the 61 placebo patients achieved that level of recovery. Patients who received the cell therapy within 36 hours after the onset of stroke did even better, with 29 percent of those 31 patients achieving an excellent outcome.

Cathy Sila, MD, Director of the Comprehensive Stroke Center at UH Case Medical Center, and Professor of Neurology at Case Western Reserve University, was the principal investigator of the study at UH Case Medical Center.

"These results are very promising and this therapy would be an important adjunct to acute <u>stroke care</u> to reduce the amount of brain injury from which patients need to recover," said Dr. Sila. "But the results are still preliminary and need to be reproduced."



Since MultiStem therapy seems to be effective when given at 24 to 36 hours after the stroke, it means many more <u>stroke victims</u> would be eligible for treatment, she said.

"Current therapy for stroke is unfortunately very limited. There is only one drug, tPA, that is FDA approved for <u>acute ischemic stroke</u>, and tPA needs to be administered within hours of onset of a stroke," said Dr. Sila. "Despite public education and the development of <u>stroke centers</u>, only about 7 percent of all <u>ischemic stroke</u> patients nationwide receive tPA therapy and less than 2 percent undergo catheter-based clot removal <u>therapy</u>. New treatments are needed to reverse the effects of a stroke and promote recovery from stroke, and they need to be effective in a wider time window to help more patients."

Ischemic stroke is caused by blockage in an artery in or to the brain, that impedes blood flow, and that can result in serious disability or even death.

MultiStem is a proprietary medication made by the Cleveland-based biotech company Athersys. The medication comes from a patented class of early adult stem cells called Multipotent Adult Progenitor Cells or MAPCs that are obtained from bone marrow. Hundreds of thousands to millions of doses can be made from the bone marrow cells of one donor. The cells do not come from the patient, so can be made in advance, stored in the hospital and be used off the shelf.

MultiStem cells appear to reduce the local inflammatory response and protect neurons in the brain, while modulating the body's general immune response and inflammation which leads to additional damage to the brain in the days immediately following the stroke. This is an entirely new concept for how cell therapies may provide benefit following central nervous system injury.



The Phase 2 study was double-blind (meaning both the patient and the doctors evaluating the patients didn't know which arm of the study the patient was in), randomized, and placebo-controlled. The study was funded by Athersys.

Provided by University Hospitals Case Medical Center

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