Stem cell therapy appears to dampen the body's neuroinflammatory response to trauma, preserve brain tissue

Published on November 4, 2016 at 8:59 AM

Results of a cellular therapy clinical trial for traumatic brain injury (TBI) using a patient's own stem cells showed that the therapy appears to dampen the body's neuroinflammatory response to trauma and preserve brain tissue, according to researchers at The University of Texas Health Science Center at Houston (UTHealth).

The results, which also confirmed safety and feasibility as cited in earlier studies, were published online Nov. 1 in the journal STEM CELLS.

"The data derived from this trial moves beyond just testing safety of this approach," said Charles S. Cox, Jr., M.D., principal investigator, the George and Cynthia Mitchell Distinguished Chair in Neurosciences at UTHealth, professor in the Department of Pediatric Surgery and co-director of the Memorial Hermann Red Duke Trauma Institute. "We now have a hint of a treatment effect that mirrors our pre-clinical work, and we are now pursuing this approach in a Phase 2b clinical trial sponsored by the Joint Warfighter Program within the U.S. Army Medical Research Acquisition Activity, as well as our ongoing Phase 2b pediatric severe TBI clinical trial - both using the same autologous cell therapy."

Cox was recently awarded $6.8 million in funding from the U.S. Department of Defense (DOD) for the Phase 2b study to assess the safety and efficacy - including whether there are structural improvements in the brain - of autologous stem cell therapy in adults with emergent traumatic brain injury. Memorial Hermann-Texas Medical Center is the site for the study.

According to the Centers for Disease Control, 1.7 million Americans sustain a traumatic brain injury annually. Of those, 275,000 are hospitalized and 52,000 die. TBI is a contributing factor to a third of all injury-related deaths in the country. According to published research cited in the paper, more than 6.5 million patients are burdened by the physical, cognitive and psychosocial deficits associated with TBI, leading to an economic impact of approximately $60 billion.

There are few current therapies to treat TBI. Critical care teams work to stabilize patients and surgery is sometimes necessary to remove or repair damaged blood vessels or tissue, as well as provide relief from swelling.

To potentially open a new avenue of treatment, Cox has been researching cell therapy for neurological disease in pre-clinical and clinical trials for more than two decades. The new study builds on his previously published research showing that autologous stem cell therapy after TBI is safe and reduces the therapeutic intensity requirements of neurocritical care. The theory is that the stem cells work in the brain to alleviate the body's inflammatory response to the trauma.

Researchers enrolled 25 patients in a dose-escalation format with five controls followed by five patients in each of three different doses followed by five more controls for a total of 25. Bone marrow harvesting, cell processing and re-infusion occurred within 48 hours after injury. Cellular processing was done at The Evelyn H. Griffin Stem Cell Therapeutics Research Laboratory at McGovern Medical School.

Functional and neurocognitive outcomes were measured and correlated with imaging data including magnetic resonance imaging (MRI) and diffusion tensor imaging (DTI) of white brain matter.

According to the authors, despite the treatment group having greater injury severity, there was structural preservation of critical regions of interest that correlated with functional outcomes and key inflammatory cytokines were down-regulated after bone marrow cell infusion.

Source:
The University of Texas Health Science Center at Houston (UTHealth)
