Boosting Stem Cells With Growth Factor May Help in Treating Critical Limb Ischemia in Hemodialysis Patients

A new type of stem cell treatment is showing promise for patients undergoing hemodialysis (HD) who suffer from critical limb ischemia (CLI). Results of a clinical trial, reported on in a recently published article in STEM CELLS Translational Medicine, show that five out of the six patients in the trial were CLI-free one year after treatment.

DURHAM, N.C. (PRWEB) July 30, 2018 -- A new type of stem cell treatment is showing promise for patients undergoing hemodialysis (HD) who suffer from critical limb ischemia (CLI). Results of a clinical trial, reported on in a recently published article in STEM CELLS Translational Medicine, show that five out of the six patients in the trial were CLI-free one year after treatment.

The study offers good news for anyone with this painful condition, which the National Center for Biotechnology Information has declared a “critical public health issue” due to its high mortality rate — exceeding 50 percent at five years after diagnosis — along with many other negative impacts on quality of life including a high rate of amputation (10 to 40 percent) and painful ulcers.

“CLI is caused by severe blockage in the arteries of the lower extremities. It can be treated with bypass surgery, but the outcome is generally poor in patients undergoing HD or who have diabetes,” said Takayasu Ohtake, M.D., Ph.D., of Shonan Kamakura General Hospital, Kamakura, Japan. He was lead author on the study in which his colleague, Shuzo Kobayashi, M.D., Ph.D., served as principal investigator.

Previous studies had examined whether transplanting autologous mononuclear cells (derived from bone marrow or peripheral blood) in these patients might help, but the results were disappointing, Dr. Ohtake said. “We know the cells have the potential for vascular regeneration,” he explained, “but their effectiveness is severely decreased in HD patients due to their uremic conditions and inflammation.”

He and his research colleagues wondered whether this deficiency might be overcome by using granulocyte colony stimulating factor (G-CSF), a type of protein that stimulates the bone marrow to produce more stem cells and deliver them to the blood stream. “We hoped this might significantly increase the number of CD34 positive cells in peripheral blood and, consequently, prove beneficial to the patients,” Dr. Ohtake said.

Six male patients with CLI were recruited for a phase II clinical trial to test their theory. Each was given a five-day series of G-CSF injections, then their stem cells were harvested from their peripheral blood, the cells were then treated and reintroduced back into the patient’s affected limb by intramuscular injections.

Dr. Ohtake said dramatic improvements were seen in a short time. “Just four weeks after treatment, ulcer size was significantly improved compared with the baseline and within 12 weeks, three out of five ulcers completely healed. At 52 weeks,” he continued, “the improvement rate from CLI stage to non-CLI stage was 83.3 percent, no amputations had to be performed and no major adverse events related to the treatment were experienced.”

“Taken together,” Dr. Kobayashi added, “these results demonstrate that G-CSF-mobilized CD34+ cell therapy is safe and dramatically improved CLI in HD patients. However, we want to caution that the small sample size and lack of control arm were major limitations in this study. Long-term observation and larger-scale clinical studies are urgently needed to further confirm the potential benefits of this cell-based therapy, particularly for
patients with life-threatening CLI who require HD.”

"These clinical trial results are certainly encouraging and demonstrate the need to further pursue this regenerative therapy to treat critical limb ischemia, a devastating disease,” said Anthony Atala, M.D., Editor-in-Chief of STEM CELLS Translational Medicine and director of the Wake Forest Institute for Regenerative Medicine. “We look forward to seeing this work continue.”

The full article, “Autologous G-CSF-mobilized peripheral blood CD34 positive cell transplantation for hemodialysis patients with critical limb ischemia: a prospective phase 2 clinical trial,” can be accessed at https://stemcellsjournals.onlinelibrary.wiley.com/toc/21576580/0/0.

About STEM CELLS Translational Medicine: STEM CELLS Translational Medicine (SCTM), co-published by AlphaMed Press and Wiley, is a monthly peer-reviewed publication dedicated to significantly advancing the clinical utilization of stem cell molecular and cellular biology. By bridging stem cell research and clinical trials, SCTM will help move applications of these critical investigations closer to accepted best practices. SCTM is the official journal partner of Regenerative Medicine Foundation.

About AlphaMed Press: Established in 1983, AlphaMed Press with offices in Durham, NC, San Francisco, CA, and Belfast, Northern Ireland, publishes two other internationally renowned peer-reviewed journals: STEM CELLS® (www.StemCells.com), celebrating its 36th year, is the world's first journal devoted to this fast paced field of research. The Oncologist® (www.TheOncologist.com), also a monthly peer-reviewed publication, in its 23rd year, is devoted to community and hospital-based oncologists and physicians entrusted with cancer patient care. All three journals are premier periodicals with globally recognized editorial boards dedicated to advancing knowledge and education in their focused disciplines.

About Wiley: Wiley, a global company, helps people and organizations develop the skills and knowledge they need to succeed. Our online scientific, technical, medical and scholarly journals, combined with our digital learning, assessment and certification solutions, help universities, learned societies, businesses, governments and individuals increase the academic and professional impact of their work. For more than 200 years, we have delivered consistent performance to our stakeholders. The company's website can be accessed at www.wiley.com.

About Regenerative Medicine Foundation (RMF): The non-profit Regenerative Medicine Foundation fosters strategic collaborations to accelerate the development of regenerative medicine to improve health and deliver cures. RMF pursues its mission by producing its flagship World Stem Cell Summit, honouring leaders through the Stem Cell and Regenerative Medicine Action Awards, and promoting educational initiatives.
Contact Information
Chelsea Kekahuna
AlphaMed Press
http://www.stemcellstm.com
+1 (919) 680-0011

Online Web 2.0 Version
You can read the online version of this press release here.