

## New therapy for heart failure may enhance body's stem cell response at cardiovascular injury site

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Dr. Leslie Miller (pointing), director of the University of South Florida Heart Institute, confirms the exact location of the catheter tip as an injection map is drawn precisely detailing gene therapy delivery sites in the heart. Credit: Photo by Daniel W. Baker, Florida Hospital Tampa

Cardiovascular disease specialists at Florida Hospital Pepin Heart Institute and Dr. Kiran C. Patel Research Institute affiliated with the University of South Florida announced they have enrolled their first patients into a clinical trial testing a novel gene therapy for the treatment of heart failure after ischemic injury. The therapy may promote the regeneration of heart tissue by encouraging the body to deploy more stem cells to the injury site.



Dr. Charles Lambert, Medical Director of Florida Hospital Pepin Heart Institute and Dr. Leslie Miller, Director of the USF Heart Institute, are leading the way for the randomized, placebo-controlled trial which spans 10 sites across the United States. The study, called the STOP-HF, will enroll 90 patients nationwide.

Heart failure (HF) can occur when the muscles of the heart become weakened and cannot pump blood sufficiently throughout the body. The injury is most often caused by inadequate blood flow to the heart resulting from chronic or acute cardiovascular disease, including heart attacks. Considerable scientific evidence has emerged over the past decade demonstrating the high therapeutic potential of regenerative medicine for a host of diseases. Heart failure is a leading cause of death, disability and hospitalization.

Dr. Charles Lambert is performing the <u>gene therapy</u> by direct injection into the heart using an investigational system in the catheterization laboratories at Florida Hospital Pepin Heart Institute.

"Pepin Heart and Dr. Kiran C. Patel Research Institute and USF are exploring and conducting leading-edge research to develop breakthrough treatments long before they are even available in other facilities," Dr. Lambert said. "Stem cells have the unique ability to develop into many different cell types, and in many tissues serve as an internal repair system, dividing essentially without limit to replenish other cells. This trial is unique in that it uses gene therapy to turn on a process leading to cell regeneration rather than simply administering stem cells directly."

The Pepin Heart Institute has a history of cardiovascular stem cell research as part of the NIH sponsored Cardiac Cell Therapy Research Network (CCTRN) as well as other active cell therapy trials. Locally, the STOP-HF trial is the first of several regenerative medicine clinical trials



teaming the USF Heart Institute with Florida Hospital Pepin Heart Institute, which is adjacent to the USF Health campus.

"This is the beginning of a new era in cardiovascular therapies," said Dr. Leslie Miller, national principal investigator for the STOP-HF trial and professor of cardiovascualar sciences at the USF Health Morsani College of Medicine. "Targeted gene and cell therapies delivered directly into the heart hold promise for helping to regenerate tissue, reduce injury and restore heart function. USF Health, working with our partners, will find new ways to diagnose and treat patients, with the aim of reducing and ultimately harnessing the global impact of heart disease."

The trial, sponsored by Juventas Therapeutics, is a double blind, randomized, placebo-controlled Phase II study evaluating the safety and effectiveness of JVS-100 in patients with ischemic heart failure. JVS-100 is the name of the gene therapy that directs the heart muscle to produce Stromal cell-Derived Factor 1 (SDF-1), a protein that has been shown to repair damaged tissue in the body through the recruitment of circulating stem cells to the site of injury, prevention of ongoing cell death and restoration of blood flow.

Earlier this year, Juventas reported results from its Phase I study in Class III ischemic <u>heart failure</u> patients. In addition to meeting the primary safety endpoint, patients in the study who received the drug demonstrated clinically significant improvements in exercise levels at the 12 month mark.

Other prominent institutions participating in the multicenter trial include Columbia University Medical Center, The University of Utah, the Lindner Center for Research at the Christ Hospital, and the Minneapolis Heart Institute Foundation.



## Provided by University of South Florida

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