



## **Novel UM Stem Cell Trial Completes Early Safety Phase**

Cardiologists at the University of Miami Health System (UHealth) have completed the early safety phase of a novel stem cell trial. The trial involves the first use in the United States of a unique injection catheter to deliver stem cells. Joshua M. Hare, M.D., F.A.C.C., professor of medicine in the Cardiovascular Division and director of the Interdisciplinary Stem Cell Institute, is leading this study which is the world's first stem cell trial comparing two cell populations, bone marrow cells and mesenchymal cells, against placebo.

This study, the Transendocardial Autologous Cells in Ischemic Heart Failure Trial (TAC-HFT), uses the Helical Infusion catheter system developed by BioCardia, a biotechnology company based in California. This is the first catheter with a spiral-shaped needle to deliver stem cells, with the goal of providing better retention of stem cells within the damaged tissue. Like other catheters, this minimally invasive method is able to inject stem cells into the heart without surgery. Stem cells have been injected surgically in other studies, including at the University of Miami, but Hare explains this “non-surgical procedure will open up the possibilities of treatment to many more patients.”

The first patient in this trial to be injected with bone marrow cells using the BioCardia catheter was treated in October 2008. He began what the Food and Drug Administration designated as a “run-in open label phase,” which is an early part of the study to establish the safety of the trial. The first four patients in the early phase have now all been treated, receiving ten injections each with .25 ml of bone marrow stem cells, not a placebo.

Alan W. Heldman, M.D., professor of medicine and vice chair for new programs and translational medicine in the Cardiovascular Division, is the interventional cardiologist responsible for the trial at the University of Miami. He has gained experience using the BioCardia Helical Injection Catheter and the Morph guiding catheter system for four years, including in clinical studies outside the U.S. He performed each of the procedures in the Miller School study.

The next phase will have four patients receive .50 ml in each of their ten injections. The first of those patients has already been treated. Once those cases are completed and safety is confirmed, the double-blind Phase I study will begin.

One group of patients in the randomized trial will get bone marrow cells, another group will get mesenchymal cells, and a third group will get a placebo. The goal is to test the ability of mesenchymal stem cells to enable the generation of new cardiomyocytes, cells that make up the tissue of the heart, to repair damaged heart tissue. Right now, physicians have no available treatments to restore the function of scarred heart tissue.

Hare and his team are hopeful that this latest milestone takes them another step closer to learning how mesenchymal stem cells might be used to treat cardiac patients. Injecting them with this minimally invasive device is “even more exciting,” says Hare. “If this approach is successful, we could potentially help tens of thousands of patients.”

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