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NEWS

DEBAKEY HEART CENTER UPDATE

METHODIST BEGINS NOVEL STEM CELL TRIAL FOR HEART FAILURE

The Methodist Hospital in Houston, Texas is the first site in the nation to enroll patients in a new study that uses a patient's own stem cells to treat heart failure.

Surgeons at the Methodist DeBakey Heart & Vascular Center will inject stem cells derived from a patient's own bone marrow directly into the beating heart to treat dilated cardiomyopathy (DCM).

"Some patients have such severe heart failure that their only current option is a heart transplant," said Dr. Brian Bruckner, cardiac surgeon at the Methodist DeBakey Heart & Vascular Center in Houston. "We hope that stem cells will stimulate angiogenesis, the growth of new blood vessels, in diseased heart tissue, and return patients to a much better quality of life without a transplant."

In the operating room, Dr. Bruckner makes three small incisions and then administers approximately 30 injections of highly-concentrated stem cells into the left side of the patient's heart.

There are currently 5.5 million people in the United States suffering from chronic heart failure. A subset of these patients has DCM, a chronic heart disease in which the patient's heart can not pump effectively enough to deliver blood and oxygen to the vital organs in the body. Patients with DCM typically experience severe limitations to physical activity and shortness of breath.

"Without a new approach to treatment of these patients, they will continue to decline and less than 40 percent will survive five years," said Bruckner, principle investigator for the trial. "We hope this trial will provide a completely new and viable treatment for them."

Dr. Michael Reardon, chief of cardiac surgery at Methodist, and Dr. Matthias Loebe, transplant surgeon at Methodist, are co-investigators on the trial.

About the trial

The IMPACT-DCM trial is a randomized, controlled, prospective, open-label, Phase I study that will seek to enroll 20 patients with ischemic dilated cardiomyopathy (DCM) and 20 patients with non-ischemic DCM at five clinical sites in the United States. The trial is sponsored by Aastrom Biosciences, Inc.

Participants must have a left ventricular ejection fraction of less than or equal to 25 percent (60-75 percent is typical for a healthy person) and meet certain other eligibility criteria.

All patients in each group will receive standard medical care and 75 percent of the patients will be treated with cardiac repair cells (CRC), a mixture of stem cells and progenitor cells derived from the patient's own blood marrow, through direct injection into the heart muscle during a minimally-invasive procedure in the operating room.

While the primary objective of this study is to assess the safety of CRCs in patients with DCM, efficacy measures including left ventricular ejection fraction and other cardiac function parameters as well as heart failure stage will be monitored. Patients will be followed for 12 months post treatment.