

Researchers test stem cell therapy for heart patients

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University of Florida doctors on Wednesday treated their first patient enrolled in a new study designed to test whether injecting stem cells into the heart helps restore blood flow to the organ by prompting new blood vessels to grow.

UF researchers plan to test the experimental therapy in people with severe coronary artery disease and daily chest pain who have not responded to traditional medications or surgical procedures designed to restore blood flow, such as angioplasty or bypass surgery.

“The general idea is that by providing these cells of blood vessel origin, we hope to either generate new blood vessels from the growth of these implanted cells or stimulate the heart to regenerate new blood vessels from the cells that reside in it,” said study investigator Carl J. Pepine, M.D., chief of cardiovascular medicine at UF’s College of Medicine. “It’s not completely clear whether it’s the actual cell itself that would do this or whether it’s just the milieu and the chemical signals that occur from the cells that would result in this.”

Each year, nearly half a million Americans with heart disease experience severe chest pain because coronary arteries and the smaller vessels that supply oxygen-rich blood to the heart muscle become narrowed or blocked by plaque deposits or clots. These blockages can trigger mini-heart attacks that, while too small to be noticed as they occur, over time irreversibly damage the heart — leading to disability, progressive heart failure or even death.

In the prospective, double-blind, placebo-controlled study, known as the Autologous Cellular Therapy CD34-Chronic Myocardial Ischemia Trial, or ACT34-CMI, UF researchers will study 15 Shands at UF medical center patients to determine whether a person's own stem cells can be used to effectively and safely treat chronic reductions in blood flow to the heart, improving symptoms and long-term outcomes. They also will evaluate whether participants report improved quality of life and exercise tolerance, and whether the heart functions better.

Participants will undergo screening tests and then receive a series of injections of a protein that releases stem cells from the bone marrow into the bloodstream. The cells, known as CD34+ stem cells, help spur blood vessel growth and are harvested from the patient during a procedure called apheresis, said Chris Cogle, an assistant professor of medicine at the UF's College of Medicine Program in Stem Cell Biology and Regenerative Medicine.

Participants will then be randomly assigned to receive one of two dosing levels of the cells, or a placebo.

“Physicians will use a catheter-based electrical mapping system to find muscle they think is still viable but not functioning,” said R. David Anderson, an associate professor of medicine at UF and director of interventional cardiology. “The cells are injected into viable sites in the heart, which have poor blood flow, in the cardiac catheterization laboratory at Shands at UF medical center.”

Patients will be periodically evaluated by echocardiography and magnetic resonance imaging over the course of a year after the procedure. Although to date study subjects have tolerated this procedure well, potential risks include infection, allergic reactions, bleeding, blood clots and damage to the heart or its vessels.

UF is one of 20 research sites participating in the national study, which is evaluating a total of 150 patients and is sponsored by the Cellular Therapies business unit of Baxter Healthcare Corp. and led by principal investigator Douglas Losordo, M.D., of Northwestern University's Feinberg School of Medicine. Baxter makes the cell-sorting equipment used to isolate the cells from the blood.

Pending Food and Drug Administration approval, UF researchers, through the National Heart, Lung and Blood Institute-funded Cardiovascular Cell Therapy Research Network, are gearing up to launch three other multicenter studies within the next several months that use other types of a patient's own stem cells.

One trial focuses on patients who have had a heart attack within a week preceding study enrollment, another focuses on patients whose heart attack occurred within the preceding two to three weeks, and the third focuses on patients with congestive heart failure or chronic chest pain that has not responded to traditional treatment.

These studies will use stem cells taken directly from the patients' bone marrow instead of stem cells isolated from the bloodstream, Pepine said, and will test whether various cell therapies can improve the heart's plumbing by helping to repair blood vessels or form new ones and strengthen the heart muscle to improve its ability to pump efficiently.

Douglas E. Vaughan, M.D., chief of the division of cardiovascular medicine at Vanderbilt University Medical Center, said the study is important and targets a challenging group of patients who need new options.

"There's a lot of enthusiasm in the cardiovascular community about the potential of cell-based therapies for the treatment of cardiovascular diseases," Vaughan said, "and there is increasing experience around the

world in using bone marrow-derived stem cells in patients with cardiovascular disease. There is growing confidence this is going to be a safe form of therapy, but there are continuing questions about how effective it will be and what its impact will be in individual patients.”

Source: University of Florida

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