Patients' Own Stem Cells May Treat Coronary Disease

By Jennifer Bails
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University of Pittsburgh Medical Center researchers announced Monday they are participating in a clinical trial to test the safety and gauge the promise of using injections of a patient's own stem cells to treat a severe form of coronary artery disease.

UPMC plans to enroll 20 patients in the Phase II trial who suffer from chronic myocardial ischemia, a potentially fatal condition where the coronary arteries narrow and restrict the flow of oxygen-rich blood to the heart. These blockages can cause severe chest pain called angina, heart attacks and progressive heart failure.

Preliminary data from an early-stage trial showed that 16 of 24 ischemia patients who received the experimental stem cell therapy reported less chest pain and an easier time exercising.

"We believe these stem cells have the capacity for regenerating more blood vessels that will replace the ones that have become blocked," said Dr. Joon Sup Lee, who directs the UPMC Cardiovascular Institute and will oversee the trial locally.

Altogether, 150 patients at 15 to 20 research sites nationwide will be enrolled in the study led by doctors at Caritas St. Elizabeth's Medical Center in Boston and sponsored by Baxter Healthcare Corp. The Illinois-based company manufactures the laboratory equipment that will be used to isolate the stem cells.

Stem cells are deployed where needed to repair normal wear and tear. By giving the heart an extra-large dose of stem cells, doctors hope to help the body do what it usually does, only better.

Patients in the study will receive a five-day course of skin injections of a protein that stimulates release of stem cells from the bone marrow into the bloodstream.

The stem cells then will be harvested from the blood through a painless procedure, called apheresis, which removes desired components from the blood and returns the rest to the body.

After processing the cells in the lab, the UPMC researchers will use a computerized navigation system to deliver them back into the heart using a thin, flexible tube with a needlelike tip called an injection catheter.

The minimally invasive procedure will take about an hour and cause mild discomfort in the groin where the catheter is inserted.

One-third of patients will receive placebo injections, another third will receive injections of 10 million cells and a third group of patients will receive 50 million cells.

UPMC doctors already have administered these treatments randomly to six ischemia patients who didn't respond to drugs and weren't candidates for conventional procedures to improve blood flow such as coronary artery bypass surgery or stent placement, Lee said.

"Certainly we haven't had any problems or complications, and some of the patients are feeling better, but it is blinded to us and them so we can't know who received what treatment until we are finished," Lee said. Results from the trial should be available in 12 to 18 months.

If the treatment proves safe and effective, the researchers could seek approval for its widespread use from the U.S. Food and Drug Administration.

Two other studies are under way at UPMC, looking at whether stem cells isolated from the bone marrow and injected into the heart through a chest incision can help patients with severe congestive heart failure, where the heart loses its pumping power.