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UM goal: Use stem cells to fix heart

BY FRED TASKER

Doctors at the University of Miami Medical School are experimenting with a radical new way of treating congestive heart failure that they hope can eventually replace heart transplants.

UM doctors have operated on the initial patient in a first-of-its kind study to determine whether adult stem cells taken from one's own bone marrow and injected directly into the heart can grow into healthy tissue and repair the damaged organ.

If the experiment works, it could bring a new course of treatment for the five million Americans affected by heart failure, which happens when the heart can't pump enough blood to the rest of the body.

"We're very optimistic," said Dr. Joshua Hare, the study's principal investigator and chief of the cardiovascular division at the medical school. The procedure worked well in earlier FDA-mandated animal trials, he said. "We had a very clear demonstration that it grows new heart tissue."

METHODS PRAISED

Dr. Doris Taylor, director of the Center for Cardiovascular Repair at the University of Minnesota, who pioneered work in stem cell heart repair when she was at Duke University, praised the UM study's aims and methods.

"Fifty percent of patients with heart failure die within five years," she said. "We need new tools. This is an idea whose time has come."

The procedure might be adapted for kidneys, pancreases, spinal cords, brain tissue and other organs, said Dr. Pascal Goldschmidt, dean of the UM Medical School. It could ease the number of cases in which patients die because there are too few transplantable organs to go around. The U.S. Department of Health and Human Services says 18 people die each day under these circumstances.

Experts outside UM say the idea is valid, but perfecting it will be a major challenge.

"We know the cells will survive in a Petri dish," said Edward Morrissey, scientific director of the Institute for Regenerative Medicine at the University of Pennsylvania. "The real key is, when you inject them into the heart, is the environment there conducive to creating new heart cells. They have a lot of things to try."

'UNIQUE' POPULATION

The 18-month study centers on 45 patients with heart failure in Miami and at Johns Hopkins University in Maryland.

It is the first such study funded by the National Institutes of Health's Specialized Center for Cell-based Therapy Initiative.

"It's a unique patient population that's never been looked at before," said Dr. Thomas Force, professor of medicine at the Center for Translational Medicine at Jefferson Medical College in Philadelphia. Force is aware of the UM study but not connected to UM.

Monday's operation was on Rodolfo Hernandez, 56, of Miami, who has congestive heart failure from an earlier heart attack. Hernandez suffers from shortness of breath and lack of energy. And he is at risk of sudden cardiac death, in which a patient dies without warning, Hare said.

About six months ago, UM doctors extracted bone marrow from Hernandez's hip. It was multiplied and purified in Petri dishes in UM labs by Ian K. McNiece, director of experimental and clinical therapies for the Stem Cell Institute.

Dr. Si Pham, professor of surgery at UM, performed triple bypass surgery on Hernandez to unblock clogged arteries. In the study, one-third of the patients get a low dose of stem cells, one-third get a higher dose and one-third get a placebo.

Neither Hernandez nor Hare knows which injection Hernandez received because the study's rules require that participants receive their treatment at random.

The 45 patients will be followed for 18 months by MRI scans to see if new heart tissue is being generated. They also will be tested to see if the heart's pumping strength and blood flow improve.

If the study shows the procedure is safe and effective, it would be followed by Phase III trials with many more patients. It means at least four to five more years of study.

Two advantages of this procedure: The patient receives stem cells from his or her own body, eliminating risk of rejection. The procedure uses "mesenchymal," or immature, adult stem cells, so no embryos are destroyed, avoiding ethical controversy.

ENCOURAGING RESULTS

Hare said he is encouraged by favorable results from a 2007 study he led at UM, Johns Hopkins and other hospitals in which stem cells were harvested from 53 heart attack patients' bone marrow, then injected into their veins. Attracted by chemical signals from inflammation from the heart attack, the cells traveled to the damaged part of the heart, improving heart function.

In the 2007 study, patients treated with the stem cells had lower rates of cardiac arrhythmias and showed improvement in heart and lung function, Hare said.

In the current study, the stem cells were injected directly into the heart during open-heart bypass surgery. Hare said doctors are working on ways to inject the cells via catheter through a major vein, avoiding open-heart surgery.

"It might even become an outpatient procedure," he said.