

Results triple researchers' projections with use of adult stem cells for heart failure

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Dr. Roberto Bolli, left, and Dr. Sohail Ikram of the University of Louisville prepare to infuse patient Mike Jones with adult cardiac stem cells. Jones was the first enrollee in the SCIPIO trial. Credit: University of Louisville

Patients suffering from heart failure due to a previous myocardial infarction showed an average of 12 percent improvement one year following an investigative treatment that involved infusing them with their own stem cells. The results triple the 4 percent improvement average the researchers projected for the Phase I trial.

Results of the trial are published today (Nov. 14) in *The [Lancet](#)* and

concurrently presented at the [American Heart Association](#) Scientific Sessions in Orlando, Fla. They are the first report of administering subjects' own cardiac stem cells in humans; previous studies have used stem cells harvested from [bone marrow](#).

The research team, led by Dr. Roberto Bolli of the University of Louisville and Dr. Piero Anversa at Brigham and Women's Hospital/Harvard Medical School in Boston, conducted the trial, called "SCIPIO" – an acronym for "Cardiac Stem Cells in Patients with Ischemic Cardiomyopathy."

The 16 SCIPIO patients were diagnosed with [heart failure](#) following a [myocardial infarction](#) and had a left ventricular ejection fraction (LVEF) of 40 percent or lower. LVEF is a standard measure of the heart's pumping capability; it measures how much blood is ejected from the left ventricle during a heartbeat. The normal LVEF is 50 percent or higher.

The investigators harvested cardiac stem cells, referred to as "c-kit positive" cells because they express the c-kit protein on their surface, from the patients during coronary artery bypass surgery conducted at Jewish Hospital in Louisville. The stem cells were purified in Anversa's lab in Boston and allowed to grow. Once an adequate number of stem cells were produced – about one million – Bolli's team in Louisville reintroduced them into the region of the patient's heart that had been scarred by the infarction.

In designing the trial, Bolli and Anversa examined data from previous studies of bone marrow-derived stem cells and projected an average improvement in LVEF of 4-5 percent for all patients. They witnessed an 8.5 percent improvement just four months following the reintroduction of [stem cells](#) and 12 percent after one year.

The researchers also conducted MRI studies on the patients' hearts and

saw that the size of the scarred regions had decreased – a result that seemingly begins to disprove the long-held belief that once scarring occurs, the heart tissue is forever dead.

Bolli – who is lead author of The Lancet article and presenter of the data at the Scientific Sessions – says that the adult stem cell protocol could become one of the greatest advancements in cardiac treatment in a generation.

"The results are striking," Bolli said. "While we do not yet know why the improvement occurs, we have no doubt now that ejection fraction increased and scarring decreased. If these results hold up in future studies, I believe this could be the biggest revolution in cardiovascular medicine in my lifetime."

His colleague Anversa has been studying cardiac stem cells' potential to regenerate myocardial cells damaged from heart failure since the 1990s. "Seeing these cells given successfully to very sick patients is the most rewarding experience that a physician-scientist can have in his or her lifetime," said Anversa, noting that the work was a major team effort that involved several senior members in both his and Bolli's laboratories.

The SCIPIO trial was funded by a grant from the National Heart, Lung and Blood Institute. The researchers reiterated that these findings are preliminary and larger-scale studies must be undertaken before the therapy can be widely used.

Bolli already is looking forward to a larger study, he said. "We plan to apply for funding to conduct a Phase II multi-center trial," he said.

More information: www.thelancet.org/

Provided by University of Louisville

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