Delayed stem cell therapy following heart attack is safe but not effective

November 14 2011

NIH-funded trial shows that therapy with bone-marrow derived cells does not improve heart function after six months; future clinical benefits still possible.

Stem cells obtained from bone marrow, known as BMCs, can be safely injected into people 2-3 weeks following a heart attack, reports a new clinical trial supported by the National, Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health. However, while safe, the BMCs did not improve heart function six months after their administration.

This study, called LateTIME (Transplantation In Myocardial Infarction Evaluation), is the first trial to rigorously examine the safety and potential benefits of extending the timing of stem cell delivery to 2-3 weeks following a heart attack. The results will be presented Monday, Nov. 14, at the 2011 Scientific Sessions of the American Heart Association Meeting in Orlando, Fla. They will also appear online in the Journal of the American Medical Association.

"Although treatment and survival following a heart attack have improved over the years, the risk of heart failure following a heart attack has not decreased," said Susan B. Shurin, M.D., acting director of the NHLBI. "Stem cell therapy is a promising direction for repairing the damage done by a heart attack. We do not fully understand the optimal use of these cells; studies like LateTIME will help us understand how to perform and monitor these procedures."

Previous studies have suggested that injecting BMCs into the heart could improve cardiac function following a heart attack and perhaps reduce the need for future hospitalizations and heart surgeries. In contrast to LateTIME, earlier studies delivered BMCs within a few days of the heart attack. In many cases, a patient will not be able to get such immediate treatment, due to poor health following a heart attack or because the hospital providing care doesn't have a stem cell therapy program.

Between July 2008 and February 2011, LateTIME enrolled 87 people with heart attacks who had undergone cardiac procedures to open blocked arteries. The participants all had moderate to severe impairment in their left ventricle, which pumps oxygen-rich blood to the body. All the participants had stem cells taken from bone marrow in their hip for processing. LateTIME researchers developed a standardized method of processing and purifying these stem cells, and this was the first BMC trial to provide a uniform dose of BMCs to each participant. The study then randomly assigned the participants to receive either their purified BMCs or inactive (placebo) cells.

After six months, improvement of heart function was assessed by measuring the percentage of blood that gets pumped out of the left ventricle during each contraction (left-ventricular ejection fraction, or LVEF) by cardiac MRI. There were no significant differences between the change in LVEF readings between baseline and six months in the BMC (from 48.7 percent to 49.2 percent) or placebo (from 45.3 percent to 48.8 percent) groups.

"This does not mean that stem cell therapy will only work if done immediately following a heart attack or that later beneficial effects on clinical outcomes won't emerge," noted Lemuel A. Moyé, M.D., Ph.D., professor of biostatistics at the University of Texas School of Public Health, Houston, and a LateTIME researcher. "Many factors influence how the heart responds to stem cells, which highlights the critical need to

continue rigorous tracking studies in this area."

Moyé added that the health of the study participants will continue to be evaluated for two years, so the BMC therapy may yet demonstrate health benefits such as a lower risk of subsequent heart attacks or heart failure, in which the heart cannot pump enough blood to meet the body's needs.

LateTIME is one of three heart stem cell trials being undertaken by the NHLBI-sponsored Cardiovascular Cell Therapy Research Network. The other trials under way by this multicenter consortium are TIME, which is comparing the effectiveness of stem cell therapy delivered at three days versus seven days following a heart attack, and FOCUS, which is examining stem cell therapy in people with chronic heart failure.

More information: Resources:

What is a heart attack: www.nhlbi.nih.gov/health/healt … /topics/heartattack/

What is heart failure: www.nhlbi.nih.gov/health/health-topics/topics/hf/

What is coronary angioplasty: www.nhlbi.nih.gov/health/healt … /topics/angioplasty/

Provided by National Institutes of Health