

Study examines treatment of heart failure with bone marrow cells

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Use of a patient's bone marrow cells for treating chronic ischemic heart failure did not result in improvement on most measures of heart function, according to a study appearing in *JAMA*. The study is being published early online to coincide with its presentation at the American College of Cardiology's annual scientific sessions.

Cell therapy has emerged as an innovative approach for treating patients with advanced [ischemic heart disease](#), including those with heart failure. "In patients with ischemic heart disease and heart failure, treatment with autologous [derived from the same individual] bone marrow [mononuclear cells](#) (BMCs) has demonstrated safety and has suggested efficacy. None of the clinical trials performed to date, however, have been powered to evaluate specific efficacy measures," according to background information in the article.

Emerson C. Perin, M.D., Ph.D., of the Texas Heart Institute and St. Luke's Episcopal Hospital, Houston and colleagues conducted a study to examine the effect of transendocardial administration (use of a special catheter and injection procedure to deliver [stem cells](#) to the [heart muscle](#)) of BMCs to patients with chronic ischemic heart disease and left ventricular (LV) dysfunction with [heart failure](#) and/or angina. The patients in the phase 2 randomized trial were receiving maximal [medical therapy](#) at 5 National Heart, Lung, and Blood Institute–sponsored Cardiovascular Cell Therapy Research Network (CCTRn) sites between April 2009 and April 2011. Patients were randomized to receive transendocardial injection of BMCs or placebo. The primary outcomes

measured for the study, assessed at 6 months, were changes in left ventricular end-systolic volume (LVESV) assessed by echocardiography, maximal oxygen consumption, and reversibility of perfusion (blood flow) defect on single-photon emission tomography (SPECT). Of 153 patients who provided consent, a total of 92 (82 men; average age: 63 years) were randomized (n = 61 in BMC group and n = 31 in placebo group).

Analysis of data indicated no statistically significant differences between the groups for the primary end points of changes in LVESV index, maximal oxygen consumption, and reversible defect. There were also no differences in any of the secondary outcomes, including percent myocardial defect, total defect size, fixed defect size, regional wall motion (the movement of the wall of the heart during contraction), and clinical improvement.

In an exploratory analysis, the researchers did find that when LVEF was assessed, patients age 62 years or younger showed a statistically significant effect of therapy. Patients in the BMC group demonstrated an average increase in LVEF of 3.1 percent from baseline to 6 months, whereas patients in the placebo group showed a decrease of -1.6 percent.

"In the largest study to date of autologous BMC therapy in patients with chronic ischemic [heart disease](#) and LV dysfunction, we found no effect of therapy on prespecified end points. Further exploratory analysis showed a significant improvement in LVEF associated with treatment. Our findings provide evidence for further studies to determine the relationship between the composition and function of bone marrow product and clinical end points. Understanding these relationships will improve the design and interpretation of future studies of cardiac cell therapy," the authors write.

More information: *JAMA*. 2012;307(16):[doi:10.1001/jama.2012.418](https://doi.org/10.1001/jama.2012.418)

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