

## Bone marrow mononuclear stem cells show no new gains in heart function, says TIME study

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New data reported by the Cardiovascular Cell Therapy Research Network (CCTRN) at the 2013 Scientific Sessions of the American Heart Association in Dallas showed that the use of bone marrow mononuclear stem cells (BMCs) did not improve heart function significantly more at one year than at six months. While there was measurable decrease in the size of scar tissue at six and 12 months, stem cells administered as a part of the TIME (Transplantation In Myocardial Infarction Evaluation) study did not improve overall heart functionality. The results were presented by Jay Traverse, MD of the Minneapolis Heart Institute Foundation on Monday, Nov. 18.

"While there are no safety issues with BMC's, the resulting reduction in scar tissue (infarct size) at six months and at one year and the small improvement in left-ventricular function was no different than a placebo, suggesting that these types of stem cells would appear to be of low therapeutic efficacy, " stated Jay Traverse, MD, of the Minneapolis Heart Institute Foundation. "At this early stage of stem cell therapy research investigating viable post-heart attack strategies, our study and others suggest that we should look at other, more potent stem cells as a means to improving functionality following a heart attack." Traverse noted that this is one of the largest serial cardiac MRI studies examining the changes in left-ventricular function following a heart attack.

In this analysis, the administration of BMC's following moderate to large



anterior STelevated <u>myocardial infarction</u> (STEMIs) was not associated with improved recovery of global and regional left ventricular (LV) function at one year compared to placebo. Levels of left ventricular ejection fraction (LVEF) increased from baseline to six months but did not improve further between six months and one year in either the BMC or the placebo group. On average, infarct size decreased in the BMC and placebo groups between baseline and six months by 30% with a smaller reduction between six months and one year. The reduction in infarct size was accompanied by a similarly significant reduction in LV mass through one year. There were no differences in the reduction in infarct size and LV mass between the BMC and placebo groups at any time.

TIME, and a previous, related study (LateTIME), were carried out by the CCTRN, sponsored by the NIH's National Heart, Lung, and Blood Institute. Both used autologous bone marrow mononuclear cells in randomized treatment of patients at different intervals following a heart attack. Together, TIME and Late TIME have shown that stem cell therapy is safe, but both studies noted a lack of effectiveness delivered by BMC therapy on left-ventricular function.

TIME was developed to examine the role of timing of cell delivery post-STEMI and enrolled 120 patients (avg. age 57) between July 2008 and February 2011; the participants all had moderate to severe reduction of their left ventricular ejection fraction (37%) and had undergone coronary stent placement as treatment for their heart attack. The participants were randomly assigned to stem cell delivery or placebo at three or seven days following their <u>heart</u> attack. Researchers utilized an automated method of processing and purifying the stem cells from the <u>bone marrow</u> of each volunteer to ensure that everyone received a uniform dose (150 million stem cells).

Provided by Minneapolis Heart Institute Foundation



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