

Evidence That Patient's Own Stem Cells Could Treat Their Heart Disease

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Preliminary data presented on March 28 as a late-breaking abstract at the American College of Cardiology's 58th annual scientific session from the largest CD34+ adult stem cell study for heart disease has shown the first evidence that delivering a potent form of autologous (from the patient) adult stem cells into the heart muscle of patients with severe angina may result in less pain and improved exercise tolerance.

The six-month, Phase II data were presented by principal investigator Douglas Losordo, M.D., director of the Feinberg Cardiovascular Research Institute and of the Program in Cardiovascular Regenerative Medicine at Northwestern Memorial Hospital. The trial was sponsored by Baxter International Inc.

"The results from this study provide the first evidence that a patient's own stem cells could actually be used as a treatment for their heart disease," said Losordo, who also is the Eileen M. Foell Professor of Heart Research at the Feinberg School. "The study provides potential hope for those patients with currently untreatable angina to be more active with less pain."

"Baxter sponsored this trial in order to continue advancing the science of adult stem cell therapies for cardiovascular disease," said Hartmut J. Ehrlich, MD, vice president of global research and development for Baxter's BioScience business. "While the preliminary results from this early- stage trial seem encouraging, further studies will be necessary to evaluate the effectiveness of this adult stem cell therapy."



Losordo also cautioned that the findings of the 26-site trial, while encouraging, are not yet definitive and require verification in a larger study. Northwestern Memorial Hospital was the lead site of the study.

This prospective, randomized, double-blind, placebo-controlled, multicenter study included 167 adult patients who were on maximal medical therapy and were not suitable candidates for conventional procedures to improve blood flow to the heart, such as angioplasty, stents, or coronary artery bypass surgery.

All patients were given a drug to stimulate release of CD34+ <u>adult stem</u> <u>cells</u> from the bone marrow, and these cells were then collected from the bloodstream using a process called apheresis. The CD34+ cells were then separated from the other blood components for use in this investigational therapy using Baxter's ISOLEX 300i Magnetic Cell Selection System, currently approved for use with cancer patients.

The CD34+ adult stem cells were injected into 10 locations in the <u>heart</u> <u>muscle</u> of patients in the treatment group. Patients in the placebo group received saline. A sophisticated electromechanical mapping technology identified where the heart muscle was alive but not functioning, because it was not receiving enough blood supply. This state is called hibernating myocardium.

"Muscle hibernates because it wants to decrease energy consumption to stay alive," Losordo explained. "It's not getting enough oxygenated blood to perform normally, so it shuts down its contractile function."

The autologous stem cell transplant is the first therapy to produce an improvement in patients with severe angina, measured by their ability to walk on a treadmill. Six months after the procedure, the autologous stem cell transplant patients were able to walk longer (average of 60 seconds) on a treadmill than the placebo group. It also took longer until they



experienced angina pain on a treadmill compared to the placebo group and, when they felt pain, it went away faster with rest. In addition, they had a reduction of episodes of chest pain compared to the control group.

Source: Northwestern University (<u>news</u> : <u>web</u>)

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