Phase Two Study Suggests Use of Adult Autologous Stem Cells May Improve Cardiac Function in Angina Patients

Baxter

CHICAGO and DEERFIELD, Ill., July 7, 2011 - New research published online today in *Circulation Research* found that injections of adult patients' own CD34+ stem cells reduced reports of angina episodes and improved exercise tolerance time in patients with chronic, severe refractory angina (severe chest discomfort that did not respond to other therapeutic options).

The phase II prospective, double-blind, randomized, controlled clinical trial was conducted at 26 centers in the United States, and is part of a long-term collaboration between researchers at Northwestern University Feinberg School of Medicine and Baxter International Inc. The objective of the trial was to determine whether delivery of autologous (meaning one's own) CD34+ stem cells directly into multiple targeted sites in the heart might reduce the frequency of angina episodes in patients suffering from chronic severe refractory angina, under the hypothesis that CD34+ stem cells may be involved in the creation of new blood vessels and increase tissue perfusion.

"Early research across multiple disease categories suggests that stem cells generated within the body in adults may have therapeutic benefit. This is the first controlled trial treating chronic myocardial ischemia (CMI) patients with their own stem cells to achieve significant reductions in angina frequency and improvement in exercise tolerance," said lead investigator Douglas W. Losordo, MD, director, Feinberg Cardiovascular Research Institute and the Eileen M. Foell Professor of Heart Research at Northwestern's Feinberg School of Medicine and director, Program in Cardiovascular Regenerative Medicine at Northwestern Memorial Hospital. "While we need to validate these results in phase III studies before definitive conclusions can be drawn, we believe this is an important milestone in considering whether the body's own stem cells may one day be used to treat chronic cardiovascular conditions."

The research team mobilized and extracted stem cells from all participants before randomizing them to one of three treatment groups: low- or high-dose cell concentrations, or placebo, and administered the regimens in 10 distinct sites in the heart tissue through a multi-point injection catheter.

At six months after treatment, patients in the low-dose treatment group reported significantly fewer episodes of angina than patients in the control group (6.8 vs. 10.9 episodes per week), and maintained lower episodes at one year after treatment (6.3 vs. 11 episodes per week). Additionally, the low-dose treatment group was able to exercise (on a treadmill) significantly longer at six months after treatment, as compared with those in the control group (139 seconds vs. 69

seconds, on average). Angina episodes and exercise tolerance rates were also improved in the high-dose treated group at six months and at one year post treatment compared to the control group.

"The concept of using one's own stem cells to treat disease is highly attractive to the medical community and this research is consistent with Baxter's commitment to driving scientific advances that can lead to promising new treatments for critically ill patients," said Norbert Riedel, Ph.D., Baxter's chief scientific officer. "These results provide important insights into the potential for these cells to be used in larger scale settings, and we look forward to moving into phase III studies in the near future to hopefully substantiate these results."

When comparing major adverse cardiac events, there was no evidence of complications related to the autologous stem cells. Three deaths occurred during the trial, one from procedural complications due to the inherent risks of cardiac surgery, the others unrelated to the treatment (all in the control group). Myocardial infarction (MI or heart attack) occurred in seven of the control group patients. There were three MIs each in the low-dose and high-dose patient groups.

Previous preclinical studies of autologous CD34+ stem cells have shown an increase in capillary density and improved cardiac function in models of acute and chronic myocardial ischemia. This phase II study is based on a phase I/II study, which provided early evidence of the feasibility, safety and bioactivity of these autologous stem cells in a similar setting.

Angina is characterized as chest discomfort due to a lack of sufficient blood supply to the heart associated with obstructive coronary artery disease (CAD). More than 850,000 patients in the United States experience refractory angina that has not responded to other therapeutic options, according to current estimates. This leads patients to reduce their activity levels significantly and negatively impacts their quality of life.

About Northwestern Memorial Hospital
Northwestern Memorial is one of the country's premier academic medical center hospitals and is the primary teaching hospital of the Northwestern University Feinberg School of Medicine. Along with its Prentice Women's Hospital and Stone Institute of Psychiatry, the hospital comprises 854 beds, 1,603 affiliated physicians and 7,144 employees. Northwestern Memorial is recognized for providing exemplary patient care and state-of-the art advancements in the areas of cardiovascular care; women's health; oncology; neurology and neurosurgery; solid organ and soft tissue transplants and orthopaedics.

Northwestern Memorial possesses nursing Magnet Status, the nation's highest recognition for patient care and nursing excellence. It is also listed in 12 clinical specialties in U.S. News & World Report's 2010 "America's Best Hospitals" guide and ranks No. 1 in Chicago in the 2010 U.S. News & World Report Best Hospitals metro area rankings. For 10 years running, Northwestern Memorial has been rated among the "100 Best Companies for Working Mothers" guide by *Working Mother* magazine. The hospital is a recipient of the prestigious National Quality Health Care Award and

has been chosen by Chicagoans as the Consumer Choice according to the National Research Corporation's annual survey for 11 years.

About Northwestern University
Northwestern University Feinberg School of Medicine, founded in 1859, attracts talented individuals to its faculty, staff, and student body through its cutting-edge research initiatives, superb clinical facilities, global outlook, and innovative curriculum. Consistently ranked high on the list of best research medical schools, Feinberg is part of the vibrant educational and cultural community of Northwestern University, an independent private institution founded in 1851, and is a central component of a premier academic medical center, Northwestern Medicine.

Located on the Northwestern campus in the heart of Chicago's Magnificent Mile, Feinberg has built a national reputation for excellence through a strong history of collaborative, interdisciplinary medical education and research. Feinberg's top-rated clinical affiliates include Northwestern Memorial HealthCare, the Rehabilitation Institute of Chicago, Children's Memorial Hospital, the Jesse Brown VA Medical Center, the Northwestern Medical Faculty Foundation, as well as numerous hospitals and clinics across the region. To learn more, visit www.feinberg.northwestern.edu [1].

About Baxter
Baxter International Inc. (NYSE: BAX), through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

This release includes forward-looking statements concerning the use of adult autologous stem cells to treat chronic myocardial ischemia (CMI), including Baxter's expectations with respect to additional phase III studies. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: timely submission and approval of anticipated regulatory filings; the successful initiation and completion of required Phase III studies; additional clinical results validating the use of adult autologous stem cells to treat chronic cardiovascular conditions; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on the company's website. Baxter does not undertake to update its forward-looking statements.

SOURCE [2]

Source URL (retrieved on *03/11/2014 - 2:26am*):

http://www.mdtmag.com/news/2011/07/phase-two-study-suggests-use-adult-autologous-stem-cells-may-improve-cardiac-function-angina-patients

Links:
[1] http://www.feinberg.northwestern.edu
[2] http://www.baxter.com/press_room/press_releases/2011/07_07_11_cmi_phase_2.html