



INNOVATION IN INTERVENTION

American College of Cardiology in co-sponsorship with SCAI

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CONTACT:
Leslie Humbel, 202-955-6222
khotz@spectrumsience.com
Amy Murphy, 202-375-6476
amurphy@acc.org
In New Orleans: (March 24-27)
Marriott Convention Center
504-613-2418

MUSCLE STEM CELLS MAY OFFER A NEW TREATMENT OPTION FOR CONGESTIVE HEART FAILURE

NEW ORLEANS, La. (March 25, 2007) — As a new wave of stem cell research continues, cardiologists are trying to tap into the self-renewing cells' life-saving potential. Scientists have performed the first U.S. controlled, randomized Phase I clinical trial using a three-dimensional guided catheter system to deliver muscular stem cells to the heart. The study was presented today at the American College of Cardiology's *Innovation in Intervention: i2 Summit* in New Orleans, La. *Innovation in Intervention: i2 Summit* is an annual meeting for practicing cardiovascular interventionalists sponsored by the American College of Cardiology in partnership with the Society for Cardiovascular Angiography and Interventions.

Patients with congestive heart failure (CHF) due to myocardial infarction (MI, or heart attack) often have scar tissue in the heart, which limits the heart's ability to pump blood. In spite of cutting-edge medical therapy and other current heart failure treatments, two million patients in the United States are admitted to the hospital for CHF each year and almost half a million die annually. Doctors may now have the opportunity to successfully replace scarred heart tissue with healthy muscle via intracardiac injections of autologous skeletal myoblasts (ASM), stem cells from the skeletal muscle.

By using a catheter and transplanting ASM into scarred tissue, living muscle can be regenerated with limited risk to the patient. Since the transplanted stem cells are harvested from

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the patient's own skeletal muscles, the cells are compatible with the body, avoiding possible immune system and tissue compatibility complications. The procedure poses less risk than surgical procedures, since no anesthesia is required and only a small incision is necessary for catheter access. Patients can be discharged within 24 hours of the procedure.

Nabil Dib, M.D., M.Sc., Director of Clinical Cardiovascular Cell Therapy at the University of California, San Diego, and Director of Cardiovascular Research of Catholic Health Care West's Chandler Regional and Mercy Gilbert Hospitals in Phoenix, Ariz., was the principal investigator of the trial, which enrolled 23 patients with poor heart function and congestive heart failure marked by progressive weakening and the inability of the heart to pump blood properly. The control group consisted of 11 patients on standard drug therapy, and the treatment group was given varying doses of 30, 100, 300, or 600 million cells of ASM. After six months, the ASM group showed marked improvement in quality of life and potential improvement in heart function, while the control group worsened. One patient with a prior history of ventricular tachycardia (abnormal heart rhythm) and pre-existing ICD implantation experienced ventricular tachycardia nine days after cell transplantation that was managed successfully.

"In this study, we learned that ASM transplantation using a minimally invasive catheter is safe, showed improvement in quality of life and may have the potential to improve cardiac function," said Dr. Dib. "To further determine the effectiveness of ASM transplantation, the FDA has granted clearance to conduct a Phase II randomized, double-blind, placebo controlled, multi-center clinical trial for up to 160 patients."

Dr. Dib will present the results of the "First United States Randomized Controlled Trial Utilizing 3-Dimensional Guided, Catheter-based Delivery of Autologous Skeletal Myoblasts for Ischemic Cardiomyopathy: Feasibility, Safety, and Improvement in Cardiac Performance" study on Sunday, March 25 at 11:15 a.m. CST in room La Nouvelle Orleans C.

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The American College of Cardiology (www.acc.org) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.07 and the i2 Summit is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.