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PRIMARY RESULTS REVEAL NO BENEFIT FOR MC-1 OVER PLACEBO IN PATIENTS UNDERGOING CORONARY ARTERY BYPASS GRAFT (CABG)
Disappointing Results from MC-1 Trial in MEND-CABG II Study

Chicago, IL--Investigators have researched a drug called MC-1, a naturally occurring metabolite of vitamin B6, to determine its efficacy in reducing myocardial injury following cardiac surgery. The results, from the MEND-CABG II Trial, did not meet their primary endpoint and showed that patients undergoing High-Risk Coronary Artery Bypass Graft (CABG) will not be able to rely on MC-1 to prevent a heart attack since researchers could not find a benefit for MC-1 over placebo. These results will be presented today at the American College of Cardiology's 57th Annual Scientific Session in Chicago, IL.

Coronary artery bypass grafting (CABG) surgery is the most commonly practiced cardiac procedure performed worldwide. In the United States, about a quarter of a million CABG procedures are performed each year. The procedures are associated with improvement in quality of life and survival in appropriately selected patients with coronary disease. CABG remains a major operation and is associated with serious complications including: myocardial infarction, stroke and death, which often occur during or immediately following the procedure.

“This was a disappointment, because we have been looking for effective therapies in these patients to prevent heart attacks. MC-1 is very safe, it's a vitamin metabolite, and is very well-tolerated. In fact there were no significant side effects associated with its use. Unfortunately, it doesn't prevent heart attacks, at least in this setting,” said the study's lead author, John H. Alexander, M.D., M.H.S., Associate Professor of Medicine in Cardiology at Duke University Medical Center and the Duke Clinical Research Institute

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in Durham, North Carolina. “It is likely that heart attacks in the peri-operative setting result from multiple different mechanisms, only one of which is reperfusion injury. Our study suggests either that MC-1 is ineffective at ameliorating ischemia reperfusion injury or that there are other reasons at play here.”

In the MEND-CABG II study, a phase three trial of MC-1, which was carried out at 130 centers in the United States, Canada and Germany, 3,023 high-risk patients undergoing CABG were randomized to MC-1 250 mg per day, or to placebo, given before bypass surgery and then continued for 30 days post-bypass. The investigators determined cardiovascular death or myocardial infarction, using a definition of myocardial infarction of CKMB 100 ng/mL, or approximately 20 times the upper limit of normal, during and immediately after CABG surgery. The incidence of heart attacks during CABG surgery, defined as an elevation of the enzyme CKMB 5, 10, or even 20 times the upper limit of normal, ranges between 10 percent and 30 percent.

One notable finding from this trial is the realization that heart attack in the setting of a bypass surgery is very common. “It is still an area of controversy, but our research has revealed that more patients suffer heart attack while undergoing CABG than we suspect clinically. We will be going back to the drawing board with renewed commitment because we really need to find a way to diminish peri-operative heart attack risk for this common and important operation.”

Dr. Alexander will present this study, “A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Cardioprotective Effects of MC-1 in Patients Undergoing High-Risk Coronary Artery Bypass graft (CABG) Surgery: Primary Results of the MEND-CABG II Trial,” on Tuesday, April 1 at 1 p.m. in North Hall B1.

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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.08 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.