TACT2 Clinical Trial Receives National Institutes of Health Funding
Second study will focus on benefits of removing toxic metal pollutants in patients with diabetes and a prior heart attack

FOR IMMEDIATE RELEASE (Miami Beach, FL – September 27, 2016) — The National Center for Complementary and Integrative Health (NCCIH) of the National Institutes of Health (NIH) has awarded $37M to Mount Sinai Medical Center of Florida and the Duke Clinical Research Institute to initiate the second Trial to Assess Chelation Therapy (TACT2). The trial is also co-funded by the National Heart, Lung and Blood Institute, the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Environmental Health Sciences.

TACT2 will examine the use of intravenous chelation treatments in combination with oral vitamins in diabetic patients with a prior heart attack to determine if they reduce recurrent heart episodes, such as heart attacks, stroke, death, and others, by removing toxins from the blood. Chelation is a process by which a medication, such as edetate disodium (Na₂EDTA), can “grab” and remove toxic metal pollutants - like lead or cadmium - which are present in most individuals.

TACT2 follows up on the positive results of TACT, an NIH-sponsored multicenter, double-blind safety and efficacy study, which took place from 2002-2012 and was conducted in 134 sites across the United States and Canada. The study chairman was Dr. Gervasio Lamas, chairman of medicine and chief of the Columbia University Division of Cardiology at Mount Sinai Medical Center in Miami Beach, Florida. During TACT, 1,708 heart attack patients were randomly assigned to receive 40 infusions of an edetate disodium-based chelation solution or a placebo (inactive) infusion. Patients also received an oral vitamin and mineral regimen, or an oral placebo.

TACT demonstrated an 18% reduction in recurrent heart events by chelation in patients who already had sustained a heart attack. Recurrent heart events measured in the study were death, heart attack, stroke, heart bypass or stent, and hospitalization for angina (chest pains). In 633 diabetic patients, there was an even larger benefit with a 41% reduction in recurrent heart events and a 43% reduction in deaths. Based on these results, the Mount Sinai and Duke scientists who conducted the trial felt that a repeat study was important to carry out.

TACT2 will narrow its focus to the group with the greatest benefit in the original study - diabetic patients 50- years of age or older who have survived a prior heart attack.

“If TACT2 is positive, it will forever change the way we treat heart attack patients and view toxic metals in the environment,” said Lamas. “Therefore, with NIH support and in collaboration with the Duke Clinical Research Institute, Columbia University, New York University, Mount Sinai (NYC), and hundreds of physicians and nurses throughout the U.S. and Canada, we are moving forward with TACT2.”

A one-year planning phase for TACT2 was conducted and included finalizing the research protocol for the trial as well as gaining NIH approval. During this phase, the investigators also identified over 100 clinical research sites in the US and Canada that aim to enroll 1,200 cumulative patients in the trial.

“The results of the original TACT study suggested that chelation of toxic environmentally-acquired metals may reduce cardiac risk, particularly in diabetic patients. If a second TACT study (TACT2) can confirm these interesting and relevant findings, it has great potential to change cardiac therapeutics.” said Valentin Fuster, MD, PhD, Physician-in-Chief for Mount Sinai Hospital in New York City and Director of Mount Sinai Heart.

Although not approved by the Food and Drug Administration for treating heart disease, some practitioners have used chelation therapy for nearly 60 years in the absence of clinical trial data supporting its use. Because of the lack of data, it has generally been believed by conventional medical practitioners and cardiologists to be without value, although TACT results suggest otherwise. A definitive answer on chelation therapy in diabetic patients that will be embraced by the cardiology community will require positive results from TACT2.

“Unless we can show a consistent effect across the two TACT Trials, it will be difficult for chelation to enter the mainstream of other cardiovascular therapies,” Lamas said.

TACT2 is currently recruiting patients for participation in the study at over 100 clinical sites throughout the U.S. and Canada. Candidates must be 50 years of age or older, have diabetes and experienced a prior heart attack. Patients interested in participating may contact the study team through [www.tact2.org](http://www.tact2.org), by calling 305-674-2260, or may contact Dr. Lamas directly at lamas@tact2.cc.

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About Mount Sinai Medical Center

Founded in 1949, Mount Sinai Medical Center is the largest independent, private, not-for-profit teaching hospital in South Florida. Mount Sinai’s mission is to provide quality healthcare to a diverse community enhanced through teaching, research, charity care and financial responsibility. Mount Sinai’s Centers of Excellence combine technology, research and academics to provide innovative and comprehensive care in cardiology, neuroscience, oncology, urology and orthopaedics. One of the original statutory teaching hospitals in the state of Florida, Mount Sinai is the hospital of choice for those who seek the level of expertise and care that only a teaching hospital can offer. Mount Sinai currently offers six convenient locations in Miami-Dade County. For more information on Mount Sinai Medical Center, visit www.msmc.com or call 305-674-CARE (2273).

About the Duke Clinical Research Institute (DCRI)

The DCRI is the largest academic research organization in the world, with a mission to develop and share knowledge that improves the care of patients through innovative clinical research. The DCRI conducts groundbreaking multinational clinical trials, manages major national patient registries, and performs landmark outcomes research. DCRI research spans multiple disciplines, from pediatrics to geriatrics, primary care to subspecialty medicine, and genomics to proteomics. The DCRI also is home to the Duke Databank for Cardiovascular Diseases, the largest and oldest institutional cardiovascular database in the world, which continues to inform clinical decision-making 40 years after its founding.