

NIH Launches Large Clinical Trial on EDTA Chelation Therapy for Coronary Artery Disease

Townsend Letter for Doctors and Patients, August-Sept, 2004

The National Center for Complementary and Alternative Medicine (NCCAM) and the National Heart, Lung, and Blood Institute (NHLBI), components of the National Institutes of Health (NIH), have launched the first large-scale clinical trial to determine the safety and efficacy of EDTA chelation therapy in individuals with coronary artery disease, the leading cause of death for both men and women in the United States.

The 5-year Trial To Assess Chelation Therapy (TACT) will involve over 2,300 patients at more than 100 research sites across the country. "The public health imperative to undertake a definitive study of chelation therapy is clear. The widespread use of chelation therapy in lieu of established therapies, the lack of adequate prior research to verify its safety and effectiveness, and the overall impact of coronary artery disease convinced NIH that the time is right to launch this rigorous study," said Stephen E. Straus, MD, NCCAM Director.

Over 800,000 patient visits were made for chelation therapy in the United States in 1997. Chelation therapy involves the use of EDTA (ethylene diamine tetra-acetic acid), a synthetic amino acid that is administered intravenously (through the veins). EDTA, which effectively speeds removal of heavy metals and minerals such as lead, iron, copper, and calcium from the blood, is approved by the US Food and Drug Administration (FDA) for use in treating lead poisoning and toxicity from other heavy metals. Although it is not approved by the FDA to treat coronary artery disease, some physicians and alternative medicine practitioners have recommended EDTA chelation as a way to treat this disorder.

Coronary artery disease (CAD) is a type of heart disease in which the coronary arteries (vessels that supply oxygen-carrying blood to the heart) become blocked by deposits of a fatty substance called plaque. As plaque builds, the arteries become narrower and less oxygen and nutrients are transported to the heart for proper function. CAD can lead to serious health problems such as angina (pain caused by insufficient oxygen-carrying blood reaching the heart) and heart attack.

There are standard and well-proven ways to reduce the risks or complications of CAD. These include stopping smoking and controlling high blood pressure and high blood cholesterol through lifestyle changes and medication. More invasive procedures are used to treat symptomatic CAD, including balloon angioplasty (dilation of a blocked artery to open it up) or coronary artery bypass surgery (using arteries or veins from other areas of the body to create detours for blood flow around areas of blockage in the heart artery).

"NCCAM's leadership in initiating and supporting this study is to be commended," said NHLBI Director Claude Lenfant, MD. "It is important for heart disease patients to know whether we should add chelation therapy to the list of proven treatments for coronary artery disease. Scientific evidence is needed to resolve this issue. And only a large clinical trial can definitively answer the question of whether chelation treatment is truly safe and effective," added Lenfant.

The randomized, double-blind study will enroll 2,372 patients aged 50 or older who have had a heart attack. The \$30 million study, led by Gervasio A. Lamas, MD, director of cardiovascular research and academic affairs at Mount Sinai Medical Center-Miami Heart Institute in Miami Beach, Florida, will test whether EDTA chelation therapy and/or high-dose vitamin therapy is effective for the treatment of CAD. Vitamin and mineral supplements, consistent with the regimen used by practitioners who deliver EDTA chelation therapy, will be used in the study.

Following baseline assessments, about 1,186 patients will be randomly assigned to receive a standardized chelation solution, and about 1,186 patients will receive a placebo (dummy) solution. Each of these two groups will additionally be randomized to receive high-dose vitamin/mineral supplements versus low-dose vitamin/mineral supplements. Study participants will receive 30 weekly infusions of EDTA chelation therapy followed by 10 bimonthly infusions. All patients enrolled will be followed until the end of the study to observe any significant clinical benefits or side effects. The primary study endpoint (a marker of improvement) of this trial will be a composite of heart attack, stroke, hospitalization for angina (pain associated with CAD), coronary revascularization, and death. The study will also evaluate cardiac deaths, nonfatal heart attacks, health-related quality of life, and cost effectiveness, among other factors.

TACT includes a Data Coordinating Center led by Kerry Lee, PhD, and a Quality of Life Coordinating Center led by Daniel Mark, MD, MPH, both at the Duke Clinical Research Institute in Durham, North Carolina. In addition, an independent Data Safety Monitoring Board will oversee the study. Patient recruitment for the study is expected to begin in March 2003, after preparations are completed to enroll participants at the many study sites.

Questions and answers about this study are located at www.nccam.nih.gov/news/2002/chelation/q-and-a.htm. Information about the study, locations, and enrollment will be available from the NCCAM Web site and from ClinicalTrials.gov, the NIH Web site for clinical trial information.

The National Center for Complementary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative medical (CAM) practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals. For additional information, call NCCAM's Clearing-house toll free at 1-888-644-6226, or visit the NCCAM Web site at nccam.nih.gov.

The National Heart, Lung, and Blood Institute (NHLBI) plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. For additional information, contact the NHLBI Health Information Center at 301-592-8573, or visit the NHLBI Web site at www.nhlbi.nih.gov.

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