



Mount Sinai  
MEDICAL CENTER

July 13, 2009

Dear TACT Participant,

First of all, I want to thank you for your continued participation in our study. You are helping us and future heart attack patients find out if chelation therapy will keep you healthier. We are writing now to give you important information about TACT.

I want to clarify that the TACT study is testing disodium EDTA in patients, like you, that have had a previous heart attack. Disodium EDTA has been in widespread use since the 1970's for disease of the heart and arteries. However, the use of disodium EDTA chelation therapy for the treatment of heart disease has never been an approved indication by the Food and Drug Administration (FDA), who have asked some companies that manufacture it to stop doing so. This is why we are performing this study (TACT), under FDA supervision.

I also want to clarify that the similar drug approved by the FDA for general use to treat lead toxicity, calcium disodium EDTA, is not the drug we use in TACT. We use disodium EDTA under a special FDA license called an IND (Investigational New Drug).

In any research study such as TACT, the safety of patients is the most important consideration, and there is very strong oversight to assure your safety. TACT is conducted under the supervision/ approval of FDA and reviewed by them yearly. TACT is also reviewed regularly by NIH and several ethics boards to make sure that the study is safe and that the rights of participants are protected. An independent Data and Safety Monitoring Board (DSMB) also oversees the study and has access to all the safety data. They meet approximately twice a year to monitor the safety of the participants throughout the course of the study. The DSMB last met on July 9, 2009 when they reviewed study data, expressed no concerns and determined that study should continue.

This information is being provided to you because we want to make sure you understand that the research drug being used, disodium EDTA, is not currently clinically indicated to be used for heart disease. This is why TACT is a research study so we can better understand EDTA as a treatment for heart disease. As the largest medical study of chelation therapy, the study will help us answer many critical questions and will assist scientists in the future.

The TACT researchers and leaders are committed to ensuring the highest level of patient safety and appreciate your ongoing commitment. We will learn more about the effects of chelation and supplements as we continue to monitor your health, and we will continue to keep you updated as new information develops.

If you have any questions or concerns, please feel free to call me at 305-674-2162 or [tactnih@aol.com](mailto:tactnih@aol.com).

Sincerely,

A handwritten signature in black ink, appearing to read "Gervasio Lamas".

Gervasio Lamas MD  
TACT Principal Investigator

TACT Clinical Coordinating Center  
Mount Sinai Medical Center | 4300 Alton Road Suite 2070-A | Miami Beach, FL 33140  
Phone: 305.674.2162 | Fax: 1-866-285TACT (8228) | [tactnih@aol.com](mailto:tactnih@aol.com)