

Randomized Comparison of High-dose Oral Vitamins vs. Placebo in the Trial to Assess Chelation Therapy (TACT)

History: Chelation therapy has been predicted to produce improvements in symptoms, endothelial function and major vascular events and reduction in atherosclerotic plaque.

Questions to answer: What are the benefits and risks of the use of both high dose vitamins/minerals and chelation therapy in patients with prior heart attacks?

Trial Design	<p>Randomized, double-blind, placebo-controlled N=1708 Randomization: 2 X 2 factorial trial; 40 infusions of a disodium EDTA-chelation solution vs. placebo AND 3 doses of oral, high dose multivitamin and mineral supplement twice daily vs. placebo F/U-over 4 years</p>	
Primary Endpoint	<p>Time to First Occurrence: Composite of all cause mortality, myocardial infarction, stroke, coronary revascularization and hospitalization for angina.</p>	
Trial Results	<p>Oral Vitamins/Minerals 27% reduction in composite primary endpoint Active/Active arm: 26% of the events</p>	<p>Placebo 30% reduction in composite primary endpoint Placebo/placebo arm :32% of events</p>
<p>Take Away: Chelation treatment, with or without supplements provides a modest reduction in cardiac events compared to a placebo treatment. The use of high-dose vitamins and mineral therapy in prior MI patients in addition to standard medical therapy to reduce the occurrence of additional cardiac events is not supported by these results.</p>		