The Trial to Assess Chelation Therapy (TACT) is a 5-year randomized, double-blind, placebo-controlled 2X2 factorial trial designed to test the effects of the standard chelation solution recommended by the American College for Advancement in Medicine (ACAM), as well as the effects of a high-dose antioxidant vitamin and mineral supplementation, versus a low dose regimen to simply replace chelation-related losses.

Specific aims for this trial include:

• To determine whether chelation or high-dose supplements in patients with CHD will reduce the incidence of clinical cardiovascular events;

• To determine whether chelation and high-dose supplements have acceptable safety profiles.

In addition, two substudies were conducted whose specific aims are as follows:

• To determine whether chelation or high-dose supplements improve quality of life;

• To conduct an economic analysis of chelation therapy and high dose supplements.

The primary endpoint of this trial is a composite of: all cause mortality, nonfatal myocardial infarction, non-fatal stroke, coronary revascularization, and hospitalization for angina.

1708 patients 50 years of age or older with a prior myocardial infarction were randomized. Following baseline assessments, patients were randomly assigned to receive 40 infusions of either the chelation or placebo solution, administered as 30 weekly infusions followed by 10 infusions administered 2 –6 weeks apart.

Please see protocol in entirety in the included document: TACT_Protocol.pdf

Overview of Data

i.   SAS Data

- .sas7bdat format
- 65 raw SAS datasets
- Unique Identifier: DEIDNUM

SAS [RAW] Dataset Name	Data Collected	Associated Page from eCRF
acttak	Action Taken with Study Infusion	16
addlab	Labs	8
addmed	Medical History	18
ae	Adverse Events	16
ae1		
basemed	Baseline Medication	6
cardhosp	Hospitalizations	11
cardio	Cardiovascular Events/Procedures	11
cardsin	Hospitalizations	30

causal	Causality	17
char	Presenting Characteristics	5
cirhosp	Circumstance for Hospitalizations for Angina	34
cirmi	Circumstances of MI	32
clincard	Cardiovascular Events, Procedures and Symptoms	25
clindat2	Clinical Data	26
clindata	Clincial Data	12
clinsmok	Cigarette Smoking Status	26
clinstat	Status of Clinic Visit	25
clinvis	Clinic Visit	25
conmed	Concomitant Medications	17
curchar	Current Characteristics	26
death	Death	29
demog	Demographics	3
discont	Discontinuations of Therapy	15
dispos	Disposition Following Infusion	12
dthadj	Death Adjudication Form	37
eos	End of Study	27
hemat	Hematology	8
herbal	Herbal Supplement Usage	7
herbsup	Herbal Supplement Usage at Visit 40	23
hospang	Angina Hospitalizations	11
hospital	Hospitalizations – Any Reason	24
imaginev	Imaging/Angiographic Evidence	2
infinfo	Infusion Information	11
infvisit	Infusion Visit	10
intcard	Interval Cardiovascular Events, Procedures and Symptoms	24
lab	Labs	8

lipid	Lipid Data	8
liver	Liver Function Data	8
markerev	Cardiac Marker Evidence	2
maxint	Maximum Intensity (AEs)	16
medhx	Medical History	5
medssin	Concomitant Medications	22
metab	Metabolic Panel Data	8
mi	MI Details	32
miadj	MI Adjudication	38
miss	Missed Visits	10
nontact	Non-TACT Dietary Supplements	24
patdem	Demographics	17
prochx	Procedure History	5
qolbase	Quality of Life Substudy Baseline Data	TACT EQOLBaseline.pdf
qolbsum		
qolfsum	Quality of Life Substudy Followup Data	TACT EQOLFollowup.pdf
qolfu		
random	Randomization/Screening Data	1
relmed	Medical History	17
sae	Serious Adverse Events	16
smoke	Cigarette Smoking Status	12
strkadj	Stroke Adjudication	39
stroke	Stroke Details	36
telefu	Telephone Follow-up	24
uumask	Unmasking Data	21
urinal	Urinalysis Lab Data	8
visit	Visits	8
vitamin	Vitamin Data	12

ii.   ANALYSIS DATA

- .sas7bdat format
- 7 Analysis [DCRI Derived] datasets
    - see TACT_Analysis_Data_Specs.pdf for derivation details
- Unique Identifier: DEIDNUM

Analysis Dataset Name	Data Collected
endpoint	Detailed endpoint data
endpts	Summary patient level endpoint data
km_endpt	Endpoint data for Kaplan-Meier plots
status2	Treatment status data
baseline	Baseline variables
subgroup	Subgroup analysis a variables
followup	Followup variables

System Requirements to Utilize SAS Data

SAS v9.4 has been used in all data manipulation and analyses. Earlier versions may work but have not been tested.

Summary of Key Variables

Please see included document: TACT_Baseline_Key_Variables.pdf for summary baseline tables from final report.