



TACT Newsletter



October 21, 2003

Message from the Principal Investigator – *Gervasio A. Lamas, MD*

Welcome to the Trial to Assess Chelation Therapy! I am proud to welcome you to an elite group of physicians and coordinators who are committed to answering an important clinical question. TACT is not just any trial – I have participated in pharmaceutical, interventional, and device trials in the past. And I can tell you that, for certain, TACT is one-of-a-kind.

TACT has had to bring to bear original solutions to knotty problems. For example, TACT is the largest and most expensive trial to test a CAM therapy. The world's only pharmacy to mix and deliver chelation (and placebo) anywhere in the US was developed for TACT. The computerized, internet-based workflow that allows hands-off calculation of EDTA dosages does not exist anywhere but TACT. The strongest collaboration of CAM physicians and conventional cardiologists is TACT. The list could go on and on.

But now it is time we bring to bear those skills with which all of us, as clinical scientists are expert: regulatory approval, screening, randomization, follow-up, and compliance. The first TACT patient was randomized on September 5, 2003 and infused on September 12, 2003 by Dr. Russell Silverman and Sherri Loucks from the Heart Care Center in East Syracuse, NY. Currently, we have 11 patients randomized.

TACT requires a lot from staff and from patients, and we recognize this. I have already had my share of patients refuse me. None of us are immune from “No, thanks, Doc.” But this is just the nature of clinical research. You push on, and interested patients will consent.

Remember we are always available to help. You can call Dr. Danielle Hollar, Dr. Steve Hussein, or me at any time to discuss a patient or a clinical issue. In the next few months we will institute a national PR campaign to inform the lay public about TACT. I have already given several interviews at local sites in order to get media exposure for TACT. So keep screening and approaching patients. Let us accelerate enrollment at all sites. Thanks.

TACT Leaders

SITES WITH RANDOMIZED TACT PATIENTS		
113	Dr. Russell Silverman/Sherri Loucks	4
217	Dr. James Carter/David Maddox	2
220	Dr. Ted Rozema /Dolly Corbin	2
115	Dr. Robert Weiss/Diane Cass	2
221	Dr. Denis Weinberg/Raquel Rojas	1

APPROVED SITES WITHOUT RANDOMIZED PATIENTS		
201	Dr. Theodore Addai/Lavenia Crutcher	
312	Dr. Tammy Born/Judy Schneider	
209	Dr. Rashid Buttar/ Nina Wall	
306	Dr. Richard Fleming/James Murphy	
406	Dr. Patrick Golden/Jeannie Buhler	
224	Dr. Angelique Hart/Dr. Adhemar Hart	
223	Dr. Roy Heilbron/Celia Heilbron	
211	Dr. Paul Kurlansky/Connie Ingram	
214	Dr. Ana Lamas/Mariana Viera Navarro	
107	Dr. Allan Magaziner/Betty Ann Persico	
305	Dr. Timothy McDonough/Lori Ackatz	
212	Dr. Joseph O'Bryan/Mary Barr	
311	Dr. Varsha Rathod/Julie Mester	
216	Dr. Ricky Schneider/Amy Abreu	
227	Dr. Sangeeta Shah/Janet Dunbar	
215	Dr. Shalendra Varma/Sharon Collins	
307	Dr. Robert Waters/Karen Fernholz	

WHO WILL RISE TO THE TOP NEXT??!

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Enrollment Tips

This exciting trial requires strong commitment on the part of patients who agree to participate. Accordingly, randomizing patients can be a challenge and may require creativity and flexibility on the part of the clinical sites. Here are some tips offered by sites which have been successful in randomizing TACT patients.

- When scheduling, offer Saturday infusions, evening infusions, or extended office hours. It's important to accommodate patients' schedules as much as possible.
- Talk about the study. You never know where you'll find your next patient.
- Make presentations to referring physicians' Grand Rounds.
- Carry your Study Pocket Card at all times while in the hospital or clinic.
- Become very familiar with the Visit Record. It provides useful summary of all randomization stages.

EQOL Update

Keep up your excellent work of administering and entering those Baseline Quality of Life Questionnaires! Any EQOL Questions?

Contact Diane Minshall-Liu:

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Preparing for a Monitoring Visit

By Wanda G. Parker, RN, MSN

Clinical Research Associate II

Study Coordinators are always busy--THIS IS A FACT. But, when a site visit is scheduled by a monitor, this is a way to validate one aspect of your site's work. The monitor would like to be efficient in completing monitoring tasks in a timely manner. The confirmation visit letter should be reviewed for the patients and documents to be monitored as well as the activities that will require the study coordinator and site investigator's presence.

Because TACT uses an internet based data capture system, the monitor will need access to a telephone line for a laptop connection and a work area. Most of the monitor's time will be spent comparing source documentation with the data in TrialMaster®. When the review process is completed, if data changes are requested (queries), the study coordinator will be asked to respond to the queries with the monitor.

The task list in TrialMaster® should be reviewed 24 hours before the visit for outstanding data entry issues. Have the following available for the monitor:

- Clinic/office chart with all source documents for the patients to be monitored (make sure any medical/hospital records needed are requested well in advance of the visit)
- Regulatory binders organized with all correspondence received in appropriate session
- Signed patient Informed consents

Remember that the monitor is there to help the site personnel with the study protocol and processes. A prepared study coordinator typically leads to a rewarding monitoring visit and a pleasant experience for all. If there are questions regarding monitoring visits, call the assigned Regional Clinical Coordinator at DCRI.

We will use this newsletter to convey study enrollment, study related updates and any educational information of interest.

Please remember to check the TACT Website (www.tactnih.com) frequently for updated information.

The user ID is 'Infusion' and the password is 'tactnih'.

TACT Communications :

TACT (DCRI) Helpline 800-545-3853

Mt. Sinai 305-674-2794

DCRI 919-668-8253