TACT TALK

September / October 2005

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Call TACT Helpline: 1-800-545-3853 (DUKE)

TACT ENROLLMENT REACHES **787** AS OF October 10, 2005 .

MESSAGE FROM DR. LAMAS . . .

Since the last time that we communicated, a lot has happened in the trial. Specifically, we have passed our 750th patient; we have enhanced safety checks for our patients in the TrialMaster system; and we have had a DSMB meeting.

So where are we in the trial? The DSMB said it all. The DSMB was pleased with the progress of the trial, and with the attention to safety that we successfully implemented. HOWEVER, at present rates of enrollment, we cannot finish before 2010, and the NIH will not support us. Therefore, if we do not increase enrollment, we will lose the trial.

What can we do? Everyone acknowledges that this is a tough trial—but that's not news. Let me suggest the following:

1. Each site must do the utmost to enroll a maximum number of patients - please end the summer doldrums.

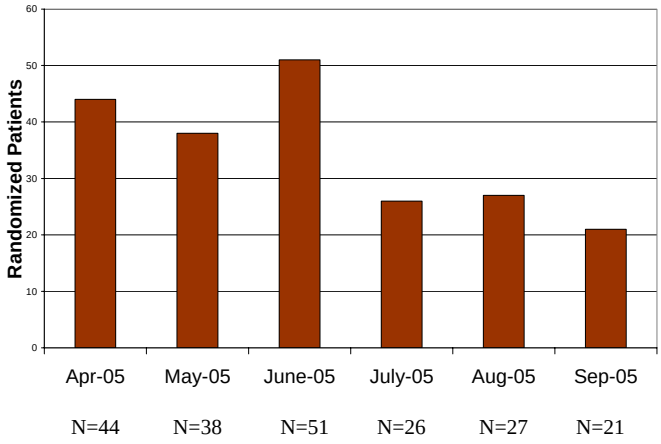
2. I want each site to identify ONE colleague who would like to be a TACT site—we need more enrollers - and have them contact me.

3. Finally, continue to keep your eye on quality and safety. We have an exemplary trial, and we want to keep it that way.

Just one more comment - please join me in wishing good health to our sites and patients in Louisiana and Texas- we hope you are safe.

Thanks. Please be in touch.

TACT Enrollment over the Past Six Months

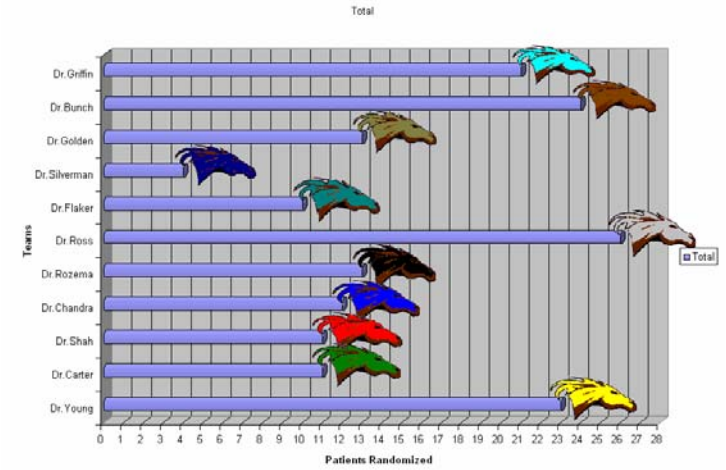


Submitted by Jason Blevins

National Center for Complementary and Alternative Medicine

TACT Site Team Derby Week 20 (August 30-Sept. 5)

Week Total = 6 TACT Total = 764



On September 10, 2003 Russell Silverman, MD and Sherri Loucks, NP-C of Heart Care Center in East Syracuse, NY (SITE #113) randomized the first TACT patient in TrialMaster® and currently has 20 patients!

Commentator: IT IS A PHOTO FINISH TRIAL FANS!!!

Dr. Ross's Team held onto the lead for the last 2 weeks and won the derby!! With an extraordinary effort Dr. Bunch's Team won second place. Dr.Young's Team, a horse length behind, won third place. Dr. Griffin's Team won fourth place. Each team was composed of eight sites. The sites listed below also won special achievement awards.

Congratulations to the winners and Thank You to all for participating in the TACT DERBY!

Site Investigators	Site #	Location	# Pts randomized during Derby	# of weeks site randomized in Derby	Total # of randomized Pts.	Award
Dr. Linda Bunch	259/272/203	West Monroe, LA	15	8	34	Leadership
Dr. Lisa Merritt	205	Lawrenceville, GA	6	6	8	Persistence
Dr. Thompson Sullebarger	255	Tampa, FL	9	5	9	Achievement
Dr. Paul Kotturan	275	Deerfield Beach, FL	5	5	5	Persistence
Dr. Charles Adams	262	Fort Oglethorpe, GA	6	5	11	Persistence
Dr. Anita Arnold	330	Milwaukee, WI	7	4	18	Teamwork
Dr. Charles Dennis	121	Browns Mills, NJ	5	5	8	Teamwork
Dr. Donald Riemer	310	Eau Claire, WI	8	3	8	Achievement
Dr. James Carter	217/228	Mandeville, LA	2	2	22	Teamwork

AWARDS:
Leadership: A leader is one who knows the way, goes the way, and shows the way
Achievement: The achievement of your goal is assured the moment you commit yourself
Teamwork: Giving a hand makes a difference
Persistence: It is wise to adopt the pace of nature, her secret is consistency and patience

Submitted by Tristan Edwards

DCC Corner

Top Five Queries

There are FIVE queries most often opened during data review:

1. Verification of prescription and refill numbers
2. Missing date of vitamin distribution
3. Missing adverse event for abnormal safety laboratory result
4. Missing inserted infusion visit iCRF for "missed visit"
5. Unresolved adverse events greater than 30 days

Careful data entry of this information can reduce your queries and save you time!

Important Reminders

1. Patient considering prematurely discontinuing the study? Call your Clinical Coordinator **BEFORE** discussing drop-out options or completing the DISCONT iCRF.

2. Collect Concomitant Medications at infusion visits 15, 30, 36 and 40 as well as at baseline.

3. Collect the name, address, phone number, e-mail address of each patient's Primary Care Physician for notification of clinical issues that arise during the patient's participation in TACT. More information and updates to TrialMaster are coming soon.

Submitted by Lindsay Lambe

Adverse Events- Helpful Hints

Please remember: The definition of an Adverse Event (AE) is any undesired, noxious or pathological change in a patient. This includes signs and symptoms or laboratory changes that occur during the course of an intervention. The documentation of these begins once study drug is begun (Infusion 1), and continues until 30 days after the final infusion. Pre-existing diseases, illness or injuries, are not considered adverse events unless there was an exacerbation, change in the frequency, or a change in the nature of these conditions. Adverse events are documented regardless of whether they are considered to be related to the study drug or not.

Become familiar with the options that are listed under each Category on the Adverse Event iCRF. Each category has a drop down box from which you may chose a 'pre-selected' entity. These fields were formatted specifically for the TACT study and may not necessarily fall within the categories you would expect... For example, you might consider 'neutropenia' to be listed under the "Laboratory Abnormalities' category, however, it is located under the category of General Body Systems. After reviewing the options for each category, please contact your Regional Coordinator if you have questions.

In the fields for **'Onset Date and Time'**, laboratory abnormalities are very easy to determine, as the date and time of blood draw are clearly identified on the requisition form. In other cases, you are dependant on the participant's report. If a time is not specified, do your best to solicit an 'approximate' time. Leading questions such as "Did it begin before breakfast", if so, when does the patient usually eat breakfast. This technique would also be helpful in determining the 'end time'. **It is important to know whether an event lasted one minute, one hour or one day.**

For events that continue after the infusion visit, complete as much of the Adverse Event form as possible. **Save the Adverse Event form as INCOMPLETE.** In this way, the form will show up under your TASK tab, under 'Incomplete iCRFs' and you will be reminded to check with the patient at the next infusion visit to determine if the event has resolved. When completed, this form does not require Investigator review and can be signed by the study coordinator.

For any questions regarding this form, or any others, please contact the DCRI. We are more than happy to provide support and guidance.

Submitted by Cresha Cianciolo and Jerry Esposito

Trial to Assess Chelation Therapy

QUESTIONNAIRE:

1- Which drugs are being tested in TACT?

2- Which patients can be enrolled in TACT?

3- How old and how recent should the MI (myocardial infarction) be to participate?

4- How old can a patient be to participate in the study?

5- How many infusions are given?

6- All patients should take drugs with proven reduction in mortality in post MI patients (i.e.: beta-blockers, aspirin, statins, and ACE inhibitors)
   A) True
   B) False

7- Renal failure is NOT a contraindication to participate:
   A) True
   B) False

8- Liver failure is a contraindication to be enrolled:
   A) True
   B) False

9- Smoking is NOT allowed in order to participate in TACT:
   A) True
   B) False

10- Thrombocytopenia leads to discontinuing future infusions:
   C) True
   D) False

ANSWERS:

1- EDTA, vitamins + mineral supplements
2- Patients post myocardial infarction
3- 6 weeks or more
4- 50 years or older
5- 40 infusions
6- True
7- False
8- True
9- True
10- False. TACT pharmacy removes heparin

Submitted by Pablo Guala

Periodic On-Site Visits

To assure that the TACT study is being conducted in accordance within FDA and Good Clinical Practices guidelines, a TACT study monitor from the DCC visits all activated sites with at least two randomized patients approximately every twelve months. Visits are scheduled in advance and conducted in an eight hour period if possible. **Since October 2003, there have been 120 on-site visits.** Here are some of the frequently observed issues and how to correct them:

Issues	Correction
Missing dates for distribution and return on Vitamin Accountability (VITACC); dates do not match dates recorded in question #21 on the Infusion Visit (INFU)	Use the Vitamin Accountability worksheet (log) found in the study manual to track distribution and return dates
Missing source documentation for the urine dip stick results	Create a source note for recording results in the patients' study file
Unresolved adverse events greater than 30 days	Leave unresolved AEs as "incomplete" as a reminder to review with each patient visit; the iCRF will be listed under your TASK tab in TrialMaster®
Missing data on the Concomitant Medication (CONMED) post visits 15, 30,36 and 40	When the TrialMaster® email your reminder that labs are required at these visits make a note for yourself to review medications with the patient
Outstanding queries	Weekly review of the TASK tab in TrialMaster® to identify and resolve queries
Missing or outdated documents filed in Regulatory Binder	Contact CCC for current versions

When you receive a telephone call from the DCRI Monitor to schedule your site visit, ask questions that will help you prepare for the visit. Preparing in advance will minimize the time needed at your site. Be sure to schedule some time for the Site Investigator to meet with the monitor at the end of the visit to review key points. A report of the findings from the site visit is sent to the site, Mt Sinai and NIH following each visit.

Submitted by Wanda Parker

CCC Corner

Our website (www.tactnih.com) has been updated! This update includes the latest versions of regulatory instructions, forms, contact lists, cardiologist letter, online study training, and revised study materials. You will also find previous issues of TACT TALK and our study commercial!

KEEP IN TOUCH by downloading our Revised Study Contact List. Regulatory Requirements . . .

- Make sure you have the latest instructions on completing any regulatory documents by downloading "Instructions for Completing Regulatory Requirements.pdf".
- Need to update your Memorandum of Agreement because your site has a new PI, new payee information, and/or has moved? Make sure to type, sign and date.
- Adding a new PI? Download the latest version of FDA form 1572.
- Need to begin screening for new patients? Or are you a new site with IRB approval and want to begin screening for new patients? Download Site Screening Log.pdf.

Alerts, Updates, Presentation Materials, Newsletters and Announcements
Download March through August TACT Newsletters and place in your study binder under "Correspondence",

Recruitment Tools and Advertising
View the TACT commercial used during the National Advertising Campaign this past summer! Use our revised letter for potential study patients who would like to speak to their cardiologist prior to joining the study.

Study Materials
Revised study materials were mailed to all sites this past summer. You can also download the revisions for your TACT Study Manual from the website.

Training a new coordinator? Need a refresher on study training? Becoming a new site? Now you can view videos and slides of all our study training online!

Submitted by Jacqueline Arcienega

SPOTLIGHT ON PATIENT RECRUITMENT

Back to Basics

With the end of summer and the coming of autumn, summer vacations are behind us, the kids are going back to school, and before we know it, the holidays will be upon us. The next couple of months are a good opportunity to get back to basics.

Dig out your patient recruitment toolkits. If you can't find it, you can view it at http://www.tactnih.com/index_rec_tool.htm. The first section includes an action plan worksheet. As you page through the toolkit, create your new action plan. Select three different strategies to employ over the next few months. You now have some first-hand experience about what has or hasn't worked in your area, and your plan should be informed by this experience.

Here are some ideas to get you started:

- Run an ad in your community newspaper. If you can, repeat the ad at least three times for greatest exposure.
- Hang flyers in local health food stores.
- Give a couple of brochures to each of your current TACT patients and ask them to pass them along to other people who might be eligible.
- Contact complementary and alternative medicine practitioners in your area (acupuncturists, chiropractors, massage therapists, etc.), educate them about TACT, and ask for patient referrals.
- Contact cardiac rehabilitation facilities in your area, educate them about TACT, and ask for patient referrals.

As always, we count on you to help make TACT a success, and we appreciate your efforts.

Submitted by Alyssa Cotler

ALL THINGS BEING EQOL…

The completion and entry of the Baseline Quality of Life forms into TrialMaster continues at an exceptional rate!

Keep up the terrific work!

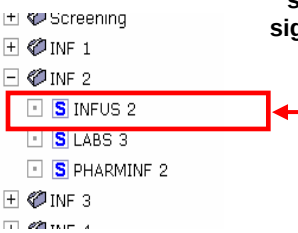
A major challenge is retaining patients in treatment and maintaining consent in the study throughout follow-up. **It's critical we follow both easy *and* difficult patients.** In order to successfully study the important questions of TACT, **we need to try as hard as possible to convert** patients who are threatening to discontinue treatment or to withdraw from the study. **We have reprinted the "CONQUER" poster (see page 6)** in this issue of TACT TALK for your review of the issues and considerations in enrolling and retaining patients.

We at the DCRI EQOL Group look for the sites' help in assisting us to locate some of the patients, reminding them of the importance of completing the QOL interview when Jason Blevins calls them, and creatively finding clinic visit times to call and get questionnaires done**. Thanks for the collaboration! Together we can fit the pieces of the puzzle and make this study happen!**

Submitted by Diane Minshall-Liu

How to Document a Missed Visit

If your patient gets their originally scheduled infusion, sign the Infusion form:

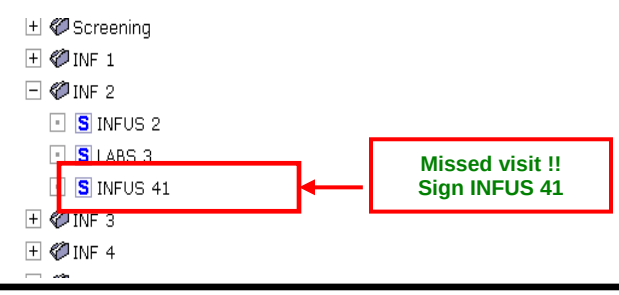


STOP! Did your patient cancel a scheduled visit and reschedule for another day? If yes, review the following:

1. If the infusion kit has been received, check the expiration date on the solution bag. If rescheduled visit is **after** the expiration date, discard the kit per your site policy.
2. Complete the scheduled visit iCRF with question # 1 response NO; only the required questions will be opened for data entry.
3. Insert another infusion visit iCRF (INFU) to use for the rescheduled visit; this form will be automatically numbered by TrialMaster®.
4. Update (reschedule) the visit in Workflow.

Patient Workflow not correct? STOP! and call your Regional Clinical Coordinator for help.

If your patient misses a visit (or receives less than 50% of their infusion) Sign the make-up Infusion form instead:



Submitted by Cherie Barnes and Lindsay Lambe

CONQUERING RETENTION OF TACT PATIENTS

NOTE: This assumes the patient was informed of the necessary *commitment* to the trial and that careful review and explanation of the consent form occurred during enrollment.

C	**CONFER WITH PATIENT** ➲	What are the issues behind the patient's wish to "refuse"/discontinue? *Listen* closely to your *patients*, as they often give clues for being upset that are hidden and not explicit.
O	**OBSERVE AND LISTEN** ➲	
N	**NEGOTIATE OPTIONS** ➲	Offer suggestions to address concerns, for example, schedule return visits at times convenient for the patient, or, if there are billing problems, offer to contact the patient accounts department. Make sure to update follow-up contact information at every visit.
Q	**QUESTION TO CONNECT** ➲	Get to know your patients, their families and physicians; involve your site investigator with the discussions. Give them your business card so they know how to call you if hospitalized, etc.
U	**UNDERSTAND "REFUSALS"** ➲	"Refusals" are a challenge to be conquered rather than an "easy out" for the patients. Their follow–up is valuable and critical whether their outcome is positive or negative. Point out that the power to analyze the effectiveness of chelation in TACT is reduced by each patient who withdraws consent.
E	**EMPATHIZE CONCERNS** ➲	Acknowledge patients' concerns or fears. Work with them to alleviate potential "refusal" situations.
R	**REASSESS & SUMMARIZE** ➲	Has the patient been "converted" to continue in TACT?, *or* will the patient discontinue: infusions? vitamins? post infusion follow-up? *or* completely withdraw consent? Please call the Clinical Coordinating Center to discuss any of these issues.