TACT TALK

March/April 2005

TACT ENROLLMENT REACHES **567** AS OF March 21, 2005…

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Clearinghouse
1-888-644-6226 (for patient referrals and to order recruitment materials)

Web Address: http://www.tactnih.com

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

Message from Dr. Lamas…

Over the last few months, I have covered many aspects of the trial, but it's time to get back to basics. Basics means enrollment. At present, our TACT team of enrolling sites is having difficulty reaching monthly enrollment rates at levels that will permit us to enroll a full complement of patients. I have spoken with each and every site, and 90% are committed to the trial and doing everything that they can. Still, some sites can do even more aggressive recruitment.

For example, I find that the efforts to engage media are uneven across sites. Dr. Shah, for example, has enrolled dozens of patients due to several TV interviews – not ads - interviews (read free media). We provide on the website a media toolkit to secure exactly the attention (free) that worked for Dr. Shah. Yet not everyone has used it. If you are uncomfortable with implementing this approach, call us, and we'll take you through it. Dr. Rozema had success putting NIH-produced, IRB-approved flyers in local health food stores. We, in a cardiology practice, are putting the flyers with our bills and clinical newsletters, and are receiving interested calls. So it takes persistence and originality.

Concrete advice

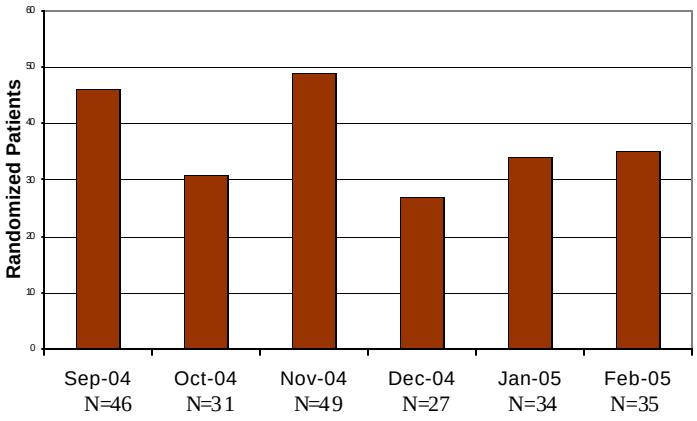
If you are a cardiology practice, you live in a river of eligible patients (pardon the metaphor). Put flyers and posters everywhere – talk to every post-MI patient; live and breathe TACT whenever you see patients. You'll succeed if you do this.

If you are a chelation site and do not have a large number of eligible patients coming through your doors each day, then you have to appeal directly to the public, and without PR efforts, you'll be dead in the water. Look at the media toolkit on the website and call us for help. Also, remember that patients often want to ask their own physician whether they should participate in TACT. Physicians hardly ever agree. Recognizing this, we have put a letter from me, to the physician of a potential TACT patient, on the website. The patient should carry this letter to his physician. I am available to speak to the physician, if you like.

Finally, we have more plans to help with PR, and I have asked each of you to identify your preferred media outlets. Stay alert – this will happen within a month, I expect. Thanks for reading this, and keep enrolling.

REMINDER: It is not only critical to enroll patients, but to enroll patients who will commit for the entire follow-up so we will have enough data at the end of the trial to be able to answer the important questions we seek to address in TACT.

TACT Enrollment over the Past Six Months



Submitted by Jason Blevins

We'll meet our target enrollment of 2,372…

IF…each site enrolls an average 1 patient/month

IF…each site enrolls an average 12 patients/year

IF…each site averages 22 patients in 22 months!

National Center for Complementary and Alternative Medicine

Congratulations to our Top 5 Enrollers!

(As of March 18, 2005)

Site	Investigator/ Coordinator	# of Patients
234	Dr. Rajiv Chandra and Terry Murphy *Tru Med in Melbourne, FL*	**46**
220	Dr. Ted Rozema and Dolly Corbin *Biogenesis Medical Center in Landrum, SC*	**31**
227	Dr. Sangeeta Shah and Traci Wilkes *Wellness and Longevity Center of Louisiana in Lafayette, LA*	**28**
239	Dr. Randy Hartman and Amy Heineman *Heart and Vascular Center for Research, Inc. in Sarasota, FL*	**21**
312/332	Dr. Tammy Born and Judy Schneider *Born Preventive Health Care Clinic in Grand Rapids, MI*	**21**

Submitted by Jewmaull Reed

Spotlight on Patient Recruitment

Kudos to those many sites that are actively seeking and securing media coverage for TACT! Just one example – recently, site # 205 in Doraville, GA planned an evening informational meeting about TACT at their clinic. They promoted TACT and the meeting to local media. As a result, the *Gainesville Times* ran an article about the study and the meeting. Several people attended the meeting to learn more and two people are enrolling in the study as a result. This activity employed the following effective strategies:

- First, by promoting an event, the story instantly became more timely and concrete, and thus more likely to be reported on.
- Second, the meeting served as a call to action for potential patients; it provided a tangible and easy activity with no long-term obligation.
- Third, by holding a meeting, the study team was able to provide in-depth information about the study to a captive audience.
- Fourth, by inviting the public to the meeting, potential participants had an opportunity to see the clinic and meet the study team, thus putting a human face on the study. The site is planning a similar meeting in early March for "gateway" organizations – that is, groups that reach and influence the patient population, including community organizations, churches, and professional associations.

Submitted by Alyssa Cotler

All Things Being EQOL….

TACT patients in EQOL Follow-up

Be sure to complete the entire Confidential Patient Information Form during screening, **AND don't forget to keep it updated** as you learn of changes in a patient's contact information. If the EQOL Interviewer is having problems contacting a patient for EQOL Follow-up, you will be called to assist in locating the patient and reminding him/her of the importance of speaking with the interviewer.

Complete Baseline QOL As Close to Randomization as Possible

The Baseline Quality of Life questionnaire should be administered on site as close to the date of randomization as possible. If it takes you weeks or months to receive medical records, or you're waiting for the patient to meet all eligibility criteria, please wait until a time closer to randomization to complete the Baseline QOL form. Patient eligibility requires laboratory results within 30 days of randomization. When the patient comes in for laboratory draws is a good time to administer the questionnaire.

Submitted by Diane Minshall-Liu

DCC Corner

Patient Follow-up

The study does not stop for patients after the first 30 infusions are completed (weekly treatment phase) or even after the last 10 infusions (maintenance phase). Patients will continue to **be followed at 3-month intervals** until the last patient enrolled completes the entire program. For patients that were enrolled at the beginning of the study (Sept. 2003) this may be up to 32 months of further 'observation'.

Please note that **after completion of the 40 infusions, the low dose gel-cap vitamins are no longer administered** but the patient will continue on the high-dose/high-dose placebo vitamins until the end of the study.

Follow-up includes annual clinical/physical examinations as well as planned telephone calls. It is expected that there will be three phone calls and one clinic visit per year. During the calls, Endpoint information is collected. The clinical exam is limited and includes cardio-pulmonary assessments and vital signs.

At each of these contact points, you should **review the demographic information** for each patient and their next-of-kin and assure that the patient has an adequate supply of high-dose/high-dose placebo vitamins. Should you have any questions about your responsibilities during the FOLLOW-UP phase, please contact your Regional Coordinator or Assistant.

Submitted by Cresha Cianciolo.

Informed Consent – More than just a form

Obtaining consent for a research study requires more than getting a signature on a piece of paper. It is a process which begins when a subject is identified and continues even after the study is completed.

The information on the consent form can serve as a guide to consenting a patient but the 'process' of consenting a patient includes any task that is necessary to ensure the patient is knowledgeable about the study and is comfortable with the benefits or consequences of their participation in the study (e.g., answering questions, providing subject time to review the consent form with family and/or friends, etc.).

Why do I have to obtain consent?
As researchers, we are legally (Code of Federal Regulations), ethically (The Declaration of Helsinki and the Belmont Report), and morally (The Nuremberg Code) obligated to ensure that each participant receives information about and understands the proposed study, has the opportunity to ask questions, and is participating voluntarily.

When should the patient sign the consent form?
Prior to <u>any</u> study related procedures. This includes any study specific labs or other tests required for inclusion.

Note: If a test that is required for inclusion in the study is part of the normal standard of care for the subject it is acceptable for the results of this test to be included in the decision to include the patient in the study even if those results were collected before the consent process.

Why bother with the consent if they won't qualify? Can't I screen them first?
No. Potential subjects must understand and voluntarily agree to the study before screening begins.

What if I forget?
Don't. Failure to comply with this regulation indicates failure to conduct the study according to Federal Regulations and any data collected will not be able to be used.

But I explained the study to the patient. I just forgot to have them sign the form.
<u>If it's not documented, it wasn't done</u>. To validate research, this dictum must be followed. This is for the protection of the patient and the research staff.

What if we may have several potential subjects whose native language is not English?
A translated version (IRB approved) of the consent document should be available for the subject and a translator should be present to answer any questions the subject may have about the consent form or the study.

DCC Corner cont.

Changing Your TrialMaster® "Signing Password"

TrialMaster® will always require the user to enter a "Signing Password" when saving a screen as SIGNED. This is the user's electronic signature. It is the one chosen as the user's "Signing Password" the first time the user logged into TrialMaster®. It should be different from the user's "Login Password."

To just change your signing password and not your system password, on the login screen check the box to change your password upon login and then click the login button. On the Change System Password screen do not enter a new password. Click the skip button; this will take you to the Change Signing Password screen. Enter your new "signing password" and confirm it. Then click the change password button. Your "signing password" has now been changed. Remember your system password has not been changed.

Remember that neither the Regional Coordinators nor the TrialMaster® Administers can change your Signing Password. Only the user can.
Submitted by Julie Glenn

Tips for Obtaining Informed Consent

- Keep a folder of blank consent forms in any place you might evaluate patients.
- Allow plenty of time to discuss the study. If you or the patients are rushed, reschedule the discussion for another day.
- Remind the patient that consenting to participate in the trial is voluntary.
- Read the protocol thoroughly so you can answer any questions for the patient. If you don't know an answer, find out before obtaining consent from the patient.
- Be sure to write a note in the patient's medical record that you discussed the study and obtained consent.
- Give the patient a copy of the signed consent form.
- Remember that consent is an ongoing process: the patient is to be informed of any new study information that might influence their willingness to participate or continue In the study.
- Familiarize yourself with the history of clinical trials to learn why consent is so important.
  NIH Guide for: *Informed Consent In Research Involving Human Participants*
  [http://grants2.nih.gov/grants/guide/rfa-files/RFA-OD-97-001.html]
- Remind the subject who they should contact if they have additional questions about the study while they are participating in the study or if they decide not to participate in the study.
- Review the difference of withdrawing from the study versus withdrawing the Authorization for the use of the subjects' data (HIPAA = Health Insurance Portability and Accountability Act) and the processes that should be followed for both.

Submitted by Lindsay Lambe