



TACT TALK

July/August 2005

TACT ENROLLMENT REACHES 728 AS OF July 27, 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)

NEW SCREENING TACTIC

As all of you know, current practice is to screen patients with previous myocardial infarction (MI) to be enrolled in TACT.

An additional source of potential TACT participants is to screen patients with prior revascularization procedures (ie: CABG and/or angioplasty). Many of these patients are often not aware if they have had an MI and are potential candidates to enroll in TACT. In fact, when we review records, we often find a scar in the perfusion images or severe wall motion abnormalities (echo/ventriculogram) that are consistent with a previous MI. This practice salvages a patient who otherwise answered NO when asked if they had sustained a prior MI.

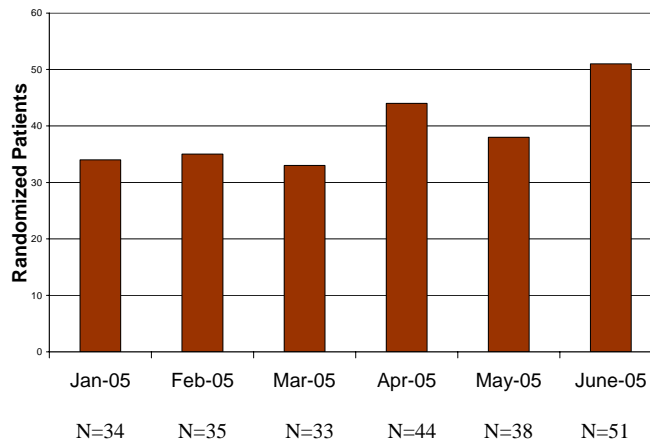
Therefore, please talk to patients who have had bypass surgery or angioplasty. When you encounter an interested post-bypass or post-angioplasty patient, look carefully at the cardiac imaging to find evidence of scar.

Finally, also take into account that records can show enzyme elevation post bypass or angioplasty, a finding that is consistent with a post procedure MI and thus qualifying the patient for TACT.

Please feel free to contact Pablo Guala, MD (Clinical Trial Manager) at 305-674-2049 with any questions.

Submitted by Dr. Pablo Guala

TACT Enrollment over the Past Six Months



Submitted by Jason Blevins



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

IF...every site enrolls an average 1 patient/month

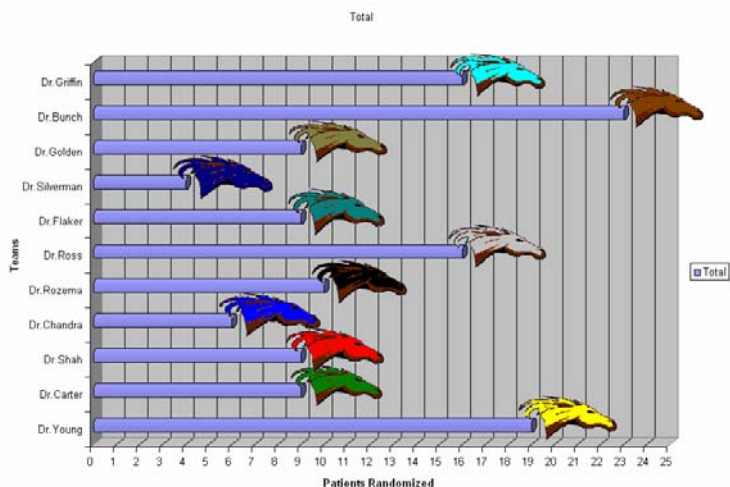
IF...every site enrolls an average 12 patients/year

IF...every site averages 13 patients in 13 months!

We can do it!



TACT Site Team Derby Week 14(July 19 – July 25)



OKAY TRIALISTS HOLD ON TO YOUR SEATS!!!!!!

- Dr. Bunch's Team is still dominating the race in first place.
- Dr. Young's Team is still fighting hard in second place.
- Dr. Ross's Team and Dr. Griffin's Team are neck to neck tied for third place.
- In a surprise move Dr. Rozema's Team has shot into fourth place.

Submitted by *Tristan Edwards*

ALL THINGS BEING EQOL...

Thanks to all for the terrific job in completing the baseline Quality of Life Questionnaire!

The challenge is to:

- Enroll patients who *fully* commit to the TACT trial.
- Retain *all* the patients through the length of the trial.
- Have *all* the data and statistical power to be able to analyze TACT!

We need your help to make this happen!

Steps to take:

- Carefully enroll patients who demonstrate understanding of the challenging requirements to participating in TACT long term.
- Completely fill out the Patient Contact Information Form, *including someone else who does not live at the patient's address*—this is critical for the follow-up phase of TACT.
- Give credence to the importance of the 3 telephone follow-ups by the interviewers at Duke University so we understand how the treatments of TACT affect the daily lives of *all* of the patients.

It's that simple and that important!

Questions? Contact Diane Minshall-Liu or Jason Blevins at Duke.

Submitted by *Diane Minshall-Liu*

From DCRI Safety Surveillance

What to do if one of your patients dies...

In an effort to keep the FDA informed of important safety issues, the NIH has requested a more conservative approach for reporting deaths for patients enrolled in TACT. All deaths, regardless of the relationship to the study intervention, require medical review and possible expedited reporting to the FDA within 7 days of the TACT team's first knowledge of the death. To ensure that the NIH and the FDA receives the most complete information, the site is required to provide complete relevant details surrounding the death. The site should complete as much of the AE, the AE Serious and the Death Details pages in TrialMaster within 24 hours of their becoming aware that a patient has died. This should include but not limited to the cause of death and the relationship to the study intervention as assessed by the site investigator. The site should continue to gather any relevant information associated with the death and answer any queries generated by DCRI Safety Surveillance. TrialMaster must be updated as soon as additional relevant information becomes available. This can be accomplished by updating the data on the AE, the AE Serious and/or the Death Details pages in TrialMaster, using the query response or by adding additional notes to the TrialMaster pages. Documents such death certificates, death/discharge summaries if the patient was hospitalized, or any clinic, emergency room or EMT/ambulance reports that were associated with the death can help you provide a complete report of a patient's death. If the patient died at home, any recent clinic notes from the patient's primary care physician should be obtained.

If you have any questions or you require assistance to report a death or any other SAE, please contact:

DCRI Safety Surveillance, phone 919-668-8624, fax 919-668-7138 or e-mail safetysurveillance@dcri.duke.edu.

Submitted by *Gerald Esposito*

DCC Corner

Patient Visit WorkFlow Tips II

After scheduling a patient's visit, check to make sure that the Visit Status column has a status of "Awaiting Prescription Shipment." This is the only status that will notify the pharmacy that the patient needs a shipment.

Before entering the patient infusion data into the Visit iCRF, check the patient's visit workflow. The Visit Status column should say "Awaiting Infusion Visit" for the infusion visit that you are entering. If the status is something other than "Awaiting Infusion Visit," do not enter the infusion information and contact the TrialMaster Administrators for help.

Always make sure that the visit you are scheduling is the correct visit. Make sure that the visit name in the workflow matches the visit that you are scheduling. Please do not schedule a new visit over the previous visit unless it was missed or the infusion wasn't given. If the visit name does not match please contact the TrialMaster Administrators for help.

If you have any questions about or problems with the Patient Visit WorkFlow, please contact the TrialMaster Administrators by email at dcri-trialmanager@mc.duke.edu

Submitted by *Julie Glenn*

Spotlight on Patient Recruitment

FAQs about the Advertising Campaign

Why an advertising campaign?

Patient randomization is a major priority for any study, and recruitment to TACT has ebbed and flowed since the trial's commencement. In an effort to stretch a limited recruitment budget, emphasis was placed on low-cost strategies that would have a high potential impact, including community outreach and centralized and local "earned" media (earned media is news coverage or articles generated by a reporter, done at no-cost to the study). In many cases, earned media generated very good response. But not all sites benefited. In spite of the hard work of all involved in the study, recruitment has fallen behind schedule. In an effort to give recruitment a much-needed boost among all sites, NCCAM authorized the TACT Clinical Coordinating Center (CCC) to invest significant resources to paid advertising.

What did the campaign entail?

Starting on May 16 and continuing through mid-June, print and television ads were placed on television and in daily and weekly newspapers in areas with TACT sites. The CCC and NCCAM placed ads in all markets with TACT sites so that all sites would have an opportunity to benefit.

How many calls from potential patients were received as a result?

The NCCAM Clearinghouse received more than 1,000 calls during the last 2 weeks of May alone. To put this in context, the typical TACT call volume is 20-30 calls per week.

How many referrals were made to sites?

The Clearinghouse made more than 600 referrals to sites. A small percentage of patients were referred to more than one site, so the number of patients referred is slightly less.

How many patients were randomized as a result?

This is unclear, and we need your help to make this determination. We know that there has been a modest bump in recruitment over the last few weeks, and we hope to see it continue to increase as patients are screened and consented. Because of the need to respect patient privacy, we do not have any way to track a specific patient; we need you to tell us where your patients heard about the study.

Will we repeat the campaign?

We do not know if the campaign will be repeated at this point. We are encouraged by the high number of calls received as a result. However, due to the time it takes for sites to obtain medical records and schedule screenings, we are not yet able to assess the campaign's ultimate effectiveness in recruiting patients. We also need to analyze which markets and outlets produced the greatest results to determine how a future campaign may be shaped.

My site is new, will you run ads in my area?

This will depend on the outcome of our analysis as to whether the ads have produced adequate results.

How can I view the ads?

You may view the print ads at http://www.tactnih.com/index_rec_tool.htm. The TV ads will be available shortly.

Can I place my own ads?

Yes, if your office budget permits. Sterling IRB-approved ads are located at http://www.tactnih.com/index_rec_tool.htm and are ready for your use. If you use a different IRB, please be sure your local IRB has reviewed and approved the ad. The typical rule of thumb is to run ads at least 3 times, so if your budget permits, plan for some repetition. Any modifications to an ad require CCC and IRB approval. If you have any questions, please contact the CCC.

What's next?

The key next step is to try to schedule screenings, secure medical documentation, and randomize any patients you may have waiting in the wings. In the meantime, the CCC and NCCAM will analyze and assess the efficacy of the campaign.

As always, thank you for your hard work on behalf of TACT!

Submitted by Alyssa Cotler

NOTICE!



Over the next couple of weeks all TACT sites will receive their first Site Report Card. Each site will receive a site specific report of their individual performance compared to the overall study. The Report Card focuses on the use of established post-MI medications (i.e. beta blockers, statins, aspirin, etc.), data quality and patient demographics. If there is a problem, your site may receive a call from the CCC to discuss post-MI medication use at your site and from your DCC Regional Coordinator to discuss data quality.

Submitted by Dr. Tony Lamas

PATIENT SAFETY TIPS



- Patients with an abnormal corrected calcium (>8.0 and <8.5 mg/dL) require infusion time to be increased to 4-5 hours.
- Consult CCC Trial Manager if patient weight increases 3lbs or more from prior infusion or increase 5lbs or more from baseline.
- Consult CCC Trial Manager if Heart Failure or Angina class worse to class III or IV.

Submitted by Dr. Tony Lamas

WHERE TO FIND HELP . . .

Helpline Information

TACT (DCRI) Helpline **800-545-3853 (DUKE)**
(Available 24 hours/day – 7 days/week)

- Urgent clinical questions
- Unmasking/unblinding
- Early discontinuation of infusions or vitamins
- Withdrawal from study

Mt. Sinai Medical Center **305-674-2162** **cccadmin@tactnih.com**

Information/questions relating to:

- Non-urgent clinical questions press “2”
- Patient eligibility press “2”
- Protocol questions press “2”
- Pharmacy (Infusion shipments, verbal orders) press “2”
- Laboratory (Quest) questions press “2”
- Site payments/contracts press “3”
- Regulatory questions press “4”
- Site start-up press “4”

You can also contact the Clinical Trial Manager for any non-urgent clinical questions, patient eligibility, pharmacy and laboratory questions directly at 305-674-2049

Study Directory

DCRI Safety Surveillance **919-668-8624**

- Reporting of Serious Adverse Events (SAEs)

DCRI Regional Site Coordinators

(Available Monday – Friday, 9:00am – 5:00pm East coast time)

Cresha Cianciolo, RN (Northeast, Midwest and West) **919-668-8973**

Mary Nahm, RN, MSN (Southeast) **919-668-8808**

Information/questions relating to:

- TrialMaster®
- Data entry
- Query resolution
- CEC source documentation
- Other miscellaneous

Economics and Quality of Life (EQOL)

Diane Minshall-Liu, CCRP, EQOL Coordinator **919-668-8221**

Jason Blevins, Interviewer / Research Analyst **919-668-8640**

Website Information

TACT Website www.tactnih.com

The TACT website contains study-wide communications and documents. It is the responsibility of the site investigator (or designee) to check the website frequently. Communications and/or documents can be downloaded, if appropriate and/or required, for placement in study regulatory (communications) binder and/or study manual.

Submitted by Jacqueline Arciniega