



TACT NEWSLETTER Special Edition

March 2004

TACT Leaders

Message from the TACT Clinical Coordinating Center

Since our last newsletter, several new sites have joined us, and we would like to take this opportunity to welcome all of you.

There are currently 101 randomized patients and we are moving toward our goal of 2372 patients.

In order to achieve success in randomizing patients, advertising is paramount. Therefore, the focus of this newsletter is articles and interviews with Investigators that have randomized patients. A press release from Dr. O'Bryan's site is also included along with a television interview with Dr. Lamas. Media interview tips are included on page 7.

Before submitting any advertisements or press releases, please make sure to send a copy to the TACT CCC for review. Upon review at the CCC, we will determine if IRB approval is needed. In addition, please notify the CCC of any future television or radio interviews one week prior to their occurrence.

We wish you well in your endeavor. Through teamwork, we will succeed. We are always here to help. Please call the CCC anytime with questions or issues you have. **Let's work together to meet our enrollment goals!**



**We can make our goal,
Continue to enroll.**

ENROLLMENT

<u>Site</u>	<u>Investigator/Coordinator</u>	<u>Patients</u>
227	Sangeeta Shah/ Janet Dunbar	18
113	Russell Silverman/ Sherri Loucks	11
220	Theodore Rozema/ Dolly Corbin	11
406	Patrick Golden/ Jeannie Buhler	11
115	Robert Weiss/ Diane Cass	7
302	Greg Flaker/ Jamie Easley	6
223	Roy Heilbron/Celia Heilbron	5
407	Nampalli Vijay/Melinda Washam	4
212	Joseph O'Bryan/Mary Barr	3
216	Ricky Schneider/ Amy Abreu	3
107	Allan Magaziner/Betty Ann Persico	2
120	Majid Ali/ Mahboobullah Baig	2
217	James Carter/ David Maddox	2
221	Denis Weinberg/ Raquel Rojas	2
232	John Griffin/ Terri Mellinger	2
234	Rajiv Chandra/ Terry Murphy	2
312	Tammy Born/ Judy Schneider	2
110	Pamela Ouyang/ Melanie Herr	1
112	Reed Shnyder/ Jean Provencher	1
215	Shalendra Varma/ Sharon Collins	1
224	Angelique Hart/Angelique Hart	1
228	James Carter/ Jodie Ledbetter	1
238	Lawrence Miller/ Deanna Overbeck	1
242	Miguel Trevino/ Tracey Osborn	1

Total 101



TACT NEWSLETTER Continued

Here is a recent article on Dr. Allan Magaziner that appeared in the GLOUCESTER COUNTY TIMES.

Chelation therapy to undergo 5-year clinical trial

Monday, March 08, 2004

By Theresa Katalinas



CHERRY HILL -- Angelo Capaldi is awaiting results of a clinical trial to prove what he has known for years. Capaldi, 77, of Turnersville credits chelation therapy -- an intravenous chemical process used to bind and remove metals or minerals from the body -- with allowing him to lead a normal life.

"I was in a wheelchair. I was losing my balance all the time. With the slightest move I would fall down," Capaldi, a diabetic with high blood pressure, recalled of life before chelation therapy began in September 2000. "Now I'm walking without the wheelchair. I'm able to do things on my own ... I even do some work around the house." Every other week Capaldi travels to The Magaziner Center for Wellness and Anti-Aging Medicine in Cherry Hill for the three-hour treatment. "It's a wonderful thing," Capaldi said. "I'll swear by it."

The center is the only Delaware Valley site selected to participate in the Trial to Assess Chelation Therapy, a \$30 million initiative sponsored by the National Institute of Health (NIH). The five-year nationwide trial is seeking 2,372 non-smokers over age 50 who recently had a heart attack, to determine the effectiveness of chelation therapy in treating cardiovascular disease.

Dr. Allan Magaziner, D.O., Magaziner Center director and American College for Advancement in Medicine president, said he has administered more than 100,000 chelation treatments over the last 17 or 18 years. He said the therapy has been in existence for about 40 years and has received approval for heavy metal toxicity. Magaziner said he uses chelation for "off-label" purposes to treat coronary artery disease. "The majority of my patients feel so good with it they don't want to give it up," Magaziner said of the \$100 treatment, not covered by health insurance because of its experimental classification. "If this study shows significant improvement ... it's quite possible that insurance would begin to cover it."

Through chelation therapy, Magaziner said he's been able to get about 50 percent of patients off heart disease medications altogether and reduce dosages of the typical three to five drugs in remaining patients. "About 90 percent have received very good to excellent results," Magaziner said. "The majority of patients come here because they've already been diagnosed with a specific problem and they're looking to prevent it from happening again."

Magaziner is seeking up to 200 patients to undergo chelation therapy as part of the NIH trial.

Therapy is free for study purposes and would involve 30 weekly intravenous treatments, followed by 10 monthly treatments, for a total of 40.

For more information, call The Magaziner Center at 424-8222.



TACT SPOTLIGHT INTERVIEW

This month's TACT spotlight interview is with Dr. Sangeeta Shah from Lafayette, Louisiana who is currently the leading TACT enroller with 18 randomized patients. Dr. Shah, a native of India, migrated with her husband to the United States in 1971. As a trained pathologist, she served in the U.S. Army as a Major in the Medical Corps at Fort Polk, Louisiana. Her military service was her gateway into Cajun country. She served as a director of the pathology department at the University Medical Center in Lafayette, Louisiana for ten years. During her pathology career, she took further training in hematopathology, helped establish a breast clinic at UMC, and served on various committees. Her passion for patient contacts and seeing all the ill effects of environmental toxicity, drug induced illness, extensive cardiovascular diseases, and death from cancer inspired her. She changed her career path and started helping patients in preventive diseases.



Q: Why have you had so much success in recruiting patients?

Initially, I had only one patient randomized in the trial. I actively sought to advertise TACT and called all of the local news media. In addition, I mailed them a brochure describing TACT and the goals of the study. One local station expressed interest in interviewing me for the study. I had the interview, which appeared on the 5:00 PM news broadcast. After that interview, I received about 30 calls and from that, I was able to randomize 16 patients.

Q: Aside from the television interview, how did you advertise for this trial? What venues did you contact?

There are many different ways to advertise this trial, including some that can be done for free. For example, I advertised in the local health magazines and the medical and dental directory, both of which were free publications. Also, with my success on the news broadcast, I am contacting the local morning news to set up an interview. Everyone has a local morning television show in his or her area. These news shows are always looking for potential news stories. Also, the target audiences is getting ready for work, looking for traffic and weather reports or if they are retired, are watching this show, so you are targeting a large audience. Another useful idea is lectures. If you have a hospital nearby with a residency program, talk to the program director about approaching the residents. You may find that you will be asked to do grand rounds, which will reach numerous physicians in the area. Also, do not forget about advertising the trial on websites that a physician may have already have established. I have done this on my own website and if people are interested, they can visit the page at the following address:

<http://www.healthybloodhealthybody.com/index.htm>. These are things that can be done by all sites.

The bottom line is to be persistent for the success of this trial. Talk to colleagues, call your local news broadcast and send out press releases.

Q: How important do you feel this trial is?

As a chelation physician, I feel it is one of the most important trials for the chelation community. Whatever the answer is, we need to find it. We need to know if it works and if so, is it because of the vitamins, the relaxation time for 3 hours while patients are receiving infusions or is it the chelation solution therapy itself. It is very important to keep this trial going but more patients are needed.

Q: Finally, how many patients do you project to enroll?

My goal is to enroll as many patients as I can. I feel that I, along with everyone else, must do his or her part in this trial to make it succeed. The only way we can succeed together is to enroll, enroll and enroll.



TACT NEWSLETTER Continued



The following transcript is from a television interview entitled Chelation Therapy with Dr. Gervasio Lamas, which appeared on the local ABC affiliate in Miami on 2/10/04.

Reporter: Chelation therapy is a controversial treatment being used to treat heart disease. It has not yet been approved by the food and drug administration for that purpose so Mount Sinai Medical center is conducting a study to find out if chelation really does work.

You're looking at 3 very different patients all with the same goal. 75-year-old JK survived a heart attack last year. 81 year old EG, had a triple bypass in 2001 and 62-year-old MB had quadruple bypass after a heart attack four years ago. Now once a week, they all come to Mount Sinai Medical Center for their chelation infusion.

Dr. Lamas: Chelation is a very controversial treatment for heart disease and disease of the arteries.

Reporter: Cardiologist Gervasio Lamas is heading up the federally funded study.

Dr. Lamas: As a traditional doctor I want to know, should I be prescribing this treatment for my patients.

Reporter: Chelation therapy uses infusions of something called EDTA. That's a synthetic amino acid believed to remove toxic metals and calcium that can build up in the blood. The theory is that it can treat coronary artery disease.

Dr. Lamas: By getting rid of some of these toxic heavy metals, it prevents and reverses the damage that some of these metals have done to the lining of the arteries.

Reporter: Patients enrolled in this 5-year study won't know if they're getting the real deal or placebo.

Dr. Lamas: I don't know what the patient's getting. The patient doesn't know and there is a 50/50 chance that there will be chelation and a 50/50 chance that there will be a placebo, an inactive preparation.'

Reporter: But for these patients who come in once a week for three hours at a time, they say it's worth it, for themselves and the future of medicine.

Patients:

EG: How else will the doctors learn unless they try these things, and they test them. So it's really an honor to be able to take part in something like this.

MB: And I would recommend it to someone else, because I feel good about it.

JK: Giving is part of receiving and I think it's fine.

Reporter: And all that said, MSMC is looking for more patients to enroll in their study. Patients must be at least 50 years of age and have had a prior heart attack. For more information on the study, call 305-674-2162 or you can simply log onto our web channel at local10.com.



TACT NEWSLETTER Continued



***** CENTURY AWARD *****

Congratulations to site 115, Dr. Robert Weiss and Diane Cass who randomized the **100th** TACT patient.

On the following page is a press release distributed by Dr. O' Bryan's group to the local news media. Since the mailing, the site has been featured in a local newspaper article. Currently, they have received over 50 calls and have also scheduled a television interview about TACT.

CLINICAL SITES NEEDED !!!!!

If you know physicians that would be interested in participating as a clinical site in TACT, please have them call Matt Shields at (305) 674 - 2794 or e-mail him at mshields@msmc.com for more information.

Richard H. Davis, MD, FACC
Richard A. Chazal, MD, FACC, FACP
Steven R. West, MD, FACC, FACP
Eliot B. Hoffman, MD, FACC
Daniel R. Schwartz, MD, FACC, FACP
James A. Conrad, MD, PhD, FACC
Michael D. Danzig, MD, FACC
David R. Axline, MD, FACC
M. Erick Burton, MD, FACC
Lawrence A. Kline, DO, FACC
William M. Miles, MD, FACC
Herman L. Spilker, MD, FACC
Paul A. Hanna, MD
Carlo D. Santos, MD, FACC, FACP, FCCP
Brian A. Hanlon, MD



Steven T. Lee, MD
Richard A. Howard, MD
Michael A. Corbellini, DO
Robert M. Grohowski, MD
Steven M. Isserman, MD
Edward A. Palank, MD, FACC
Thomas H. Kreulen, MD, FACC

RESEARCH CENTER

Joseph P. O'Bryan, MD

Gary E. Shidel, MSN, ARNP
Linda Cifani, MSN, ARNP
Doreen Kline, MSN, ARNP
Bonnie Sealey, MSN, ARNP

FOR IMMEDIATE RELEASE –
03/02/04

The Southwest Florida Heart Group is please to announce their participation in TACT (Trial to Assess Chelation Therapy), the first large-scale, nationwide clinical trial of a controversial alternative treatment for heart disease. The five-year federally-funded clinical trial is being sponsored by the National Institute of Health and the National Center for Complementary and Alternative Medicine. Joseph P. O'Bryan, MD is the Principal Site Investigator for the Southwest Florida Heart Group.

The trial will assess chelation's effect on heart disease. Chelation involves injecting a synthetic amino acid, EDTA, into the bloodstream to remove harmful heavy metals from the body. A simplified explanation of chelation is this: the body needs essential minerals, such as copper and iron, to perform properly. But the buildup of heavy metals, such as mercury and lead, may increase the formation of free radicals and cause oxidation, the same process that causes junkyard iron to rust. Proponents of chelation believe that this "rusting" process in the body may lead to inflammation in the blood vessels and thus may cause coronary artery disease, the leading cause of death in the United States. Despite criticism of this alternative therapy by mainstream medicine, many patients swear that chelation has improved their health and makes them feel better.

Chelation treatment is approved by the United States Food and Drug Administration (FDA) for lead poisoning and toxicity from other heavy metals, but it has not been approved to treat coronary artery disease, which is the purpose of this study. The study's goal is to enroll 2372 patients nationwide, age 50 or older who have had a heart attack but have not received chelation therapy in the last 5 years. Patients will be randomly assigned to receive chelation with high-dose vitamins or a placebo solution (inactive substance) with the same vitamin and mineral supplements. Patients will receive weekly treatments for 30 weeks followed by 10 more treatments at two-week intervals. These treatments and all study-related medical care are free of charge to the patient.

The Southwest Florida Heart Group is also conducting a variety of other clinical drug and device trials for coronary heart disease, congestive heart failure, high cholesterol, and atrial fibrillation. Many of these trials test experimental medications or devices to treat these conditions.

Currently 70 patients have enrolled in the TACT chelation trial nationwide, so more volunteers are needed. For more information, or if you are interested in volunteering to participate in this clinical trial you may contact:

Joseph P. O'Bryan, MD, Southwest Florida Heart Group Clinical Research Center, 239-433-8880, or www.heart.research@swfheartgroup.com

National Center for Complementary and Alternative Medicine, (888) 644-6226, <http://nccam.nih.gov> or <http://clinicaltrials.gov>

TACT Communication

TACT (DCRI) Helpline 800-545-3853

Mt. Sinai 305-674-2794

DCRI 919-668-8253



MEDIA INTERVIEW TIPS

The following tips will help you prepare for a media interview in print, radio, and television.

- **Be prepared.** Before granting an interview, first ask who will be conducting the interview, what the topic is, the length of the interview, what the format is (e.g., for radio is it live or taped) who else is being interviewed, what information they are looking for, and what the reporter's deadline is. Then, arrange a time to speak.
- **Practice.** Role-play likely questions to prepare for the interview, referring to your messages to be sure you're making key points.
- **Have confidence.** At any interview, relax, listen and think. Take time to form your response before speaking and deliver messages with confidence.
- **Headline your answers.** Like it or not, we live in a sound bite culture. You must deliver a key message within the first 15 seconds of your answer, then support your message with examples or proof points.
- **Keep it balanced.** Remember, this is a controversial topic. Your job is not to sell chelation therapy. We are conducting this study because the effectiveness of chelation therapy has not yet been scientifically proven. As more and more people turn to chelation therapy, we need the public's help to find the answer to this important public health issue.
- **Keep it simple.** Speak clearly and simply, using language that is descriptive. Avoid jargon, acronyms, or too much technical language.
- **Keep it brief.** Loose lips sink ships during the interview process. If you have answered the question succinctly, do not continue to over-answer the question. Your message will get lost in too much dialogue.
- **Don't fear silence.** Once you have answered a question, stop talking and do not be afraid of ensuing silence. Let the reporter fill the pause – it's often a ploy to get you to say more than you planned.
- **Flag key points.** Emphasize your key points. Examples include: "What I want to emphasize is...", "The main point here is...", "The bottom line is...", "The important thinking for consumers to know is...".
- **Never fake an answer.** Never lie to a reporter or try to bluff an answer you do not know.



● Know your goal for the interview and what you want to say. Create simple messages and review these messages until they are top-of-mind. Be able to cite statistics and sources to add meaningful support