

**Maxine Mesinger
Multiple
Sclerosis
Clinic**

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The MS Messenger

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Research Issue: The Future of MS

By George Hutton, MD

Clinical Research Director, Maxine Mesinger Multiple Sclerosis Clinic, Baylor College of Medicine



There are now six FDA-approved drugs available to treat various forms of multiple sclerosis. Most of these are approved for treatment of relapsing forms of MS. However, these drugs are only partially effective, and there is an ongoing need for continued clinical research to investigate new therapeutic options for MS. At the Maxine Mesinger MS Clinic, we have been involved with about 15 MS clinical trials over the past several years. Several of the ongoing trials will be discussed below.

The FDA has established a vigorous process for new drug development, in order to ensure the safety and efficacy of approved drugs. The average drug takes over 10 years to go through this process. There are several phases of clinical trials you may hear about. Phase 1 trials are usually conducted in a relatively small group of healthy volunteers to determine the tolerability of the

drug. The emphasis in phase 2 trials is on effectiveness. This often involves comparing a new drug against a placebo in a group of patients with MS. The primary outcome in phase 2 MS trials is the effect of the drug on brain MRI. These trials tend to involve several hundred patients. If a drug shows good results in phase 2 trials, it will proceed to a phase 3 trial. Phase 3 trials are larger, usually done at multiple MS centers, and need to look at clinical outcomes as the primary outcome. Most drugs in phase 3 trials are compared against placebo. In these MS trials, the main outcomes evaluated include relapse rate reduction, and reduced disability. A drug can be considered for FDA approval based on favorable results in at least one phase 3 trial (although they may require two trials). Phase 4 trials are done after the drug is already on the market, but may look at long term safety and efficacy, new combinations, etc. Most clinical trials *randomize* patients to one specific treatment arm. This means patients are placed into groups randomly, and neither the patient nor the doctor

can assure placement in a particular treatment group.

One phase 3 trial which is currently enrolling patients is the CombiRx trial, which is a large, multi-center trial sponsored by the National Institutes of Health (NIH). This trial is investigating the potential benefit of combined treatment with Avonex and Copaxone in patients with relapsing MS. This trial is open only to patients who have not previously taken Copaxone or an interferon drug.

We are also enrolling patients into a phase 2 trial of a product called Tovaxin, which is a T cell vaccination cellular product. It has the potential advantage of being a cell-based product which is generated for an individual MS patient to combat their specific immune system problem. This technology and research was originally started at Baylor College of Medicine in the early 1990s and a previous phase 1 trial was completed here in the late 1990s. It is now being developed by a company in The Woodlands, and we were the
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Meet The Staff: Clinic research staff



Wini Breitbach, RN, MSCN is the nurse coordinator for clinical trials at the clinic. As a MS Certified Nurse, she also assists Dr. Rivera

with patient care & is an instructor in the Neurology Department of the Baylor College of Medicine. Ms. Breitbach, who is the longest practicing MS nurse in the country, was born & raised in North Dakota where

she graduated from St. Alexius School of Nursing in Bismark ND. She has held numerous nursing & supervisory positions at hospitals in ND, Michigan, Colorado and Houston. Ms. Breitbach has contributed to research in cardiovascular surgery (including heart transplantation and aortic balloon), microscopic neurosurgery, neurovascular disease, ALS, epilepsy, migraine and most importantly, MS. She has published at least 16 papers in major medical journals and presented at

numerous national & international meetings and held many committee appointments for organizations such as the National MS Society. Over the years she has refined her many personal interests which include cooking (& eating!) reading, sewing and painting landscapes (as well as her home a time or two.) Most of us know Wini from her dedication to her two beloved dogs, Maxine and Emil (called Maxie & Emi) and she loves to joke that they have her "well trained!"

Research (Continued from page 1)

first trial site to enroll patients for the current phase 2 trial. This is a multi-center placebo controlled trial. Eligible patients must have relapsing MS for 10 years or less and must be off other MS drugs (such as Copaxone or interferons). 1/3 of patients will receive placebo and 2/3 will receive Tovaxin for the one year duration of the trial. Participants will have a relatively large amount of blood drawn and sent to the central lab to see if they can identify T cells which react against myelin proteins. T cells are a certain type of white blood cell. Not all patients with MS will have such reactive T cells, and those who do not will not be able to

continue in the study. After such reactive T cells are found they will be expanded (cloned) and then inactivated by exposure to a source of radiation. These inactivated T cells are then given back to the same patient as a T cell vaccination. The concept is that your body's immune system will then recognize these inactivated T cells as abnormal and will fight against them, and in doing so will also fight against the other reactive T cells in your body.

These are just 2 examples of some of the clinical trials for which we are currently enroll-

ing patients. We are also doing several trials to investigate cognitive (memory, thinking) problems in MS. One of these will involve a computer assisted cognitive rehabilitation program in conjunction with Dr. Francisco Perez, a neuropsychologist. The goal in this trial is to help MS patients with cognitive problems to improve by participating in a computer-based cognitive rehabilitation program, much of which is done as "homework" over the internet from the patient's home.

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Meet the Staff (continued from page 1)



Shell Laday-Thibodeaux, LVN is a Senior Clinical Research Coordinator. She attended Lamar University in Port Arthur TX & was licensed in 1987 by the Texas Board of Nurses. Until recently, the majority of her nursing experience was in Oncology & Infectious Diseases. Shell has 10+ years in the field of research & has worked on numerous clinical trials. She joined the research team at the clinic 2 years ago assisting Dr. Hutton and Dr. Rivera with clinical trials; and has

enjoyed developing personal relationships with the patients and staff who are like family to her.

Jeanene DeLaRosa is a Research Coordinator. She graduated with a Law Enforcement and Criminal Justice degree & was working in that field when she decided to make a career change 9 years ago. Thanks to a tip from a good friend, Jeanene took a job at Baylor College of Medicine assisting Dr. Jingwu Zhang in the Neurology Department with his T-cell vaccination study & managed

research grants for the department as well. In June 2005, another opportunity to work with MS patients became available at the clinic so she joined the research team where she currently assists Dr. George Hutton with 6 different trials. Also, as a Certified Phlebotomist, she provides expert assistance obtaining blood samples ordered by the physicians and is often complimented for her ability to make the experience as quick and painless as possible. Jeanene, like Shell, enjoys her work at the clinic & the connections she has made with the patients she serves.

Community Events

2006 MS Walk

Did you know that 200,000 participants nationwide raised \$50 million last year to help the world get closer to finding a cure for MS?

*There are lots of ways to participate in this year's walk. Contact the NMSS @ 713/526-8967 or check out the NMSS website for more info @ www.nmss.org. **Here are the four walk locations***

this year:

Katy
8 a.m. Saturday, Oct. 21, 2006
*Katy Mills Mall
Great inside venue for those with MS and their families;
1-mile loop inside mall*

Kemah
8 a.m. Saturday, Oct. 21, 2006
*Kemah Boardwalk
1-mile and 5K routes*

Woodlands
9 a.m. Saturday, Oct. 21, 2006
*Panther Creek Shopping Center
5-mile loop
Fun Run: \$25 registration fee*

Downtown Houston
8 a.m. Sunday, Oct. 22, 2006
*Sam Houston Park
1-mile and 5K routes*

Community Events (continued from page 2)

Abilities Expo-Texas

December 1-3, 2006
George R. Brown Convention Center
Houston, TX

Show Hours:

Friday: December 1 10:00 am - 5:00 pm

Saturday: December 2 10:00 am - 5:00 pm

Sunday: December 3 11:00 am - 5:00 pm

The exhibition will feature independent and assisted living products and services developed to improve the lives of persons with disabilities.

You will be able to test and compare products and services offered by a variety of organizations and companies. One special offer is complimentary wheelchair repair by Hands On Concepts at their booth on a first come, first served basis. Abilities Expo also offers FREE consumer

and professional workshops by leading individuals in the healthcare, education, and retail fields.

Tickets are \$5 and children under 12 are free. However, if you log onto the website www.tex.abilitiesexpo.com

and click on "Ticket Info" you can print out a form; fill out the requested information, and bring it with you to the event for FREE admission.

Getting involved in your community can enhance your physical and emotional well-being!

Health & Wellness

WEST GRAY ADAPTIVE RECREATION CENTER (formerly called the West Gray Multi-Service Center)

1475 W. Gray

Services provided at no cost include:

recreational & sports programs, **wheelchair accessible**

workout facilities and free health equipment,

accessible swimming pool heated to 89 degrees with therapeutic and aquatic exercise (keep in mind that there is usually a waiting list for pool programs and your physician will usually need to complete a referral form),

adult and children's art classes,

accessible landscaped park trail with community fruit & vegetable garden, **vocational & employment services** and **case management services.**

For more information, call 713/284-1973.

Research (continued from page 2)

Clinical trials are very important as they help advance the understanding of multiple sclerosis and may lead to new (and hopefully better) medications. However, clinical trials are not right for everyone. Some people do not feel comfortable with the idea of being involved in trials, especially ones in which there is a chance of assignment to a placebo group. Each trial has very

specific criteria regarding which patients can be involved, including limits on age, duration of disease, type of disease, and other medications which someone is on or has been on in the past.

We thank all of our patients who have been involved in our many trials. There is a whole group of professionals involved in helping to run these trials here in the clinic. This includes the physicians and research fellows, col-

leagues in Psychiatry and neuropsychology, our nurses, research coordinators, social worker, and others. Our goal is to provide excellent care to our patients, including the opportunity to be involved with the latest research into new treatments for multiple sclerosis.



Baylor College of Medicine

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Comments or suggestions? Contact
Tracey Reeves @ 713/798-4470.

“Making life livable for persons with MS.”

National MS Society Corner

MEDICARE PART D FALL ENROLLMENT PERIOD IS APPROACHING...

Before you sign up or re-enroll, consider calling the National MS Society. The organization offers assistance to Medicare recipients with MS who are navigating the program choices & wish to make an informed decision about their prescription drug coverage.

Counseling is provided by telephone at 1-877-524-4044 & if you live in Austin, Dallas, Houston or San Antonio, you can also make an appt. for in-person counseling which is offered be-

tween 10am-2pm on the 2nd Thursday of the month.

Advocacy Matters

Consider sharing your personal story involving Medicare Part D on the National MS Society website www.nmss.org or by calling 1-800-524-4044. Your comments help state and federal legislators understand the true impact of legislation on persons with MS.

FREE YOGA

The National MS Society sponsors an adaptive yoga class every Monday from 6:30-7:30 pm at the JCC Merfish Center

located at 9000 S. Rice, 77096. If you are interested, please RSVP weekly the Friday prior to class by calling 713-526-8967.

VOLUNTEERS WITH MS EMPOWERMENT DAYS

Don't forget about the opportunity to get involved in the MS community by volunteering at the Lone Star Chapter Headquarters in Houston every third Tuesday of the month. Contact Kelly Engle @ 713/526-8967 for more information.

LOOK FOR PICTURES OF NMSS FAMILY DISCOVERY CAMP IN THE NEXT ISSUE!