

CLINICAL TRIALS UPDATE

By Herbert S.B. Baraf, M.D.

Why would anyone want to be a patient in a clinical trial? That is a question many people ask themselves. In 23 years of operation, our Center for Rheumatology and Bone Research has treated more than 3000 patients in clinical trials. Study patients have expressed appreciation for the special attention they receive in the study setting, the opportunity to learn more about their rheumatic disease process, the chance to receive treatments not otherwise available, and the ability to help in the development of safer and more effective therapies.

There have been some recent reports in the news of mishaps, improper physician conduct and institutional abuses. Yet, more frequently these same media sources trumpet the benefits of new advances in therapy for a variety of different diseases. In fact, there have been astonishing therapeutic advances recently in virtually every field of medicine. How do these advances come about? Through the clinical trials process, of course! And for every successful drug studied, there are hundreds of patients who have benefited early on in the course of drug development. Indeed, many of you reading this article have profited greatly from these advances, either by participating in one of our studies or by receiving a new drug proven to be effective in trials conducted at our facility.

A prostate cancer patient, writing to the Washington Post in February, decried the press negativism and reflected on his experience with clinical trials.

He wrote, "...First, I got a much more accurate diagnosis (than I did in my HMO.). ...Second, they offered me treatment in a clinical trial of a refinement of a standard technique that was known to be effective against my type of cancer. ...Third, they gave me outstanding attention and care. ...The therapies they used ...were expertly applied by highly ...trained medical professionals who were handling small numbers of patients with large numbers of staff and ample amounts of time. ...Finally, they did all of this for free. There was no payment, no co-pay, no insurance premium, or charges for records." Noting that his research physician was having difficulty recruiting enough patients for this trial, the writer lamented, "apparently the great majority of people in the Washington area would prefer to wrestle with their insurers, accept assembly line medicine, wait long weeks for doctors appointments, receive care from low paid staff and low bidder medical labs, and pay for the privilege."

At the Center for Rheumatology and Bone Research, we are very proud of the work we have done to help bring new and important therapies to our patients. With our patients' involvement, we remain at the spearhead of the successful development of dozens of important, life-altering, new arthritis therapies, including: Enbrel, Remicade, Humira, Kineret, Vioxx, Celebrex, Bextra, Evoxac, Fosamax, Actonel and Evista.

At present, we are recruiting patients for participation in a diverse group of programs.

Current Clinical Trials

GOUT:

We have two projects actively seeking patients.

- The first evaluates a new medication to lower the blood uric acid level. A high uric acid level in the blood causes gout. The new medication will be tested in patients with severe chronic gout who are unsuccessfully controlled with, or unable to tolerate, available uric acid lowering drugs. Patients will receive a stipend to participate.
- The second is for patients with an acute attack of gout. If you have gout that suddenly flares, please consider calling us immediately to see if you qualify. Patients will receive a stipend to participate.

RHEUMATOID ARTHRITIS:

Several trials for patients with RA are under way.

- We are seeking patients for an evaluation of a Chinese herbal therapy for rheumatoid arthritis. Chinese Thundergod Vine is being compared to Azulfidine for disease modifying effectiveness.
- We are beginning a trial comparing standard therapies for early rheumatoid arthritis. This is an outstanding opportu-

nity for patients who have not yet been started on methotrexate. We are comparing methotrexate alone to two other combinations of disease modifying drugs, all of which are currently FDA approved. Costs of medicines are all covered.

- Patients with arthritis that is active in spite of full dose methotrexate therapy are candidates for participation in one of two trials evaluating antibodies directed against lymphocytes.
- Patients with anemia related to their rheumatoid arthritis may be candidates to participate in a trial of a hormone that stimulates red blood cell production.

**OSTEOARTHRITIS
(Degenerative Joint Disease):**

- Osteoarthritis of the knee or hip is the subject of five clinical trials. These trials all differ from one another. Patients will receive a stipend to participate.

ANKYLOSING SPONDYLITIS:

- We are evaluating the effect of Humira - a TNF inhibitor approved for patients with rheumatoid arthritis - in the management of Ankylosing Spondylitis.

**SYSTEMIC LUPUS
ERYTHEMATOSUS:**

- Patients with active lupus may be appropriate for a trial of an inhibitor of lymphocyte function.

OSTEOPOROSIS:

- We are currently screening patients for several new osteoporosis treatments.

If you are interested in participating in our clinical trials program, please speak with your physician or contact the Center for Rheumatology and Bone Research directly at 301-942-6610. Our patient recruiter, Linda Gargiulo, will be pleased to provide you with information and the opportunity to answer any questions you may have.

If you or someone you know would like to learn more about our clinical trials program, call our study department at (301) 942-6610 or return this card to:

**THE CENTER FOR RHEUMATOLOGY AND BONE RESEARCH
2730 UNIVERSITY BLVD. WEST, SUITE 306, WHEATON, MD 20902**

I am interested in learning more about participating in a clinical trial.

Name: _____ Phone #: _____

Address: _____ Best time to reach you: _____

_____ Your Physician _____

Diagnosis and/or symptoms? _____
