SOUTHWESTERN NEWS

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ARTHRITIS RESEARCHERS WILL DO EXCLUSIVE AMERICAN CLINICAL TRIAL ON JAPANESE DRUG

DALLAS — November 22, 1993 — Arthritis researchers at The University of Texas Southwestern Medical Center at Dallas have begun the first American clinical trial of bucillamine, a rheumatoid-arthritis drug manufactured in Japan.

A primary focus of the research will be to determine if bucillamine is safe. UT Southwestern researchers will study the mechanism of the drug's immunosuppressive effects and try to determine the dose that will most effectively decrease the physical symptoms and serologic-cell activity in rheumatoid-arthritis patients.

Bucillamine is related in composition to penicillamine, which is an approved rheumatoid-arthritis treatment drug in the United States. However, significant structural differences may make the Japanese drug a more potent immunosuppressant than its Western cousin. Preliminary research also indicates that the new drug acts more quickly and has fewer side-effects.

This will be the largest study ever conducted by UT Southwestern's rheumatic-diseases division, said Lisa Nichols, clinical-research coordinator and primary developer of the clinical trial guidelines. Researchers expect to enroll 80 to 100 patients during a two-year period.

Researchers have begun the study by administering the drug to 12 patients. This control group is being studied to evaluate the effectiveness of the dosage being administered. Open enrollment of the remaining patients will begin on Feb. 1.

Study subjects will be recruited from patients presently being treated for rheumatoid arthritis at the Dallas Department of Veterans Affairs Hospital, UT Southwestern's James W. Aston Ambulatory Care Center, Parkland Memorial Hospital and the referral clinic in the offices of the rheumatic-diseases division.

People 18 to 70 years old who suffer from mild arthritis and those with more severe rheumatoid arthritis who have failed to respond to other available treatments

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are eligible.

Before participating in the 20-week study with bucillamine or a placebo, patients who are taking medications such as penicillamine, methotrexate or hydroxychloroquine must go without them for a month. "Many of these drugs take a long time to work, and they also stay in your system for a period of time after you stop taking them," Nichols explained.

Santen Pharmaceuticals of Osaka, Japan, will provide the drug. UT Southwestern has received permission from the U.S. Food and Drug Administration to conduct the study, Nichols said.

The principal investigator is Dr. Peter Lipsky, director of the Harold C. Simmons Arthritis Research Center and professor of internal medicine and microbiology. Working with Lipsky are Drs. John Cush and Arthur Kavanaugh, assistant professors of internal medicine.

To be considered for enrollment in the study, call (214) 648-7658.

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