SOJTHWESTERN NEWS

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UT Southwestern lead site for study of a new multiple sclerosis drug

DALLAS – April 26, 2005 – UT Southwestern Medical Center is the lead research site testing a new treatment for a rare form of multiple sclerosis. Called "primary progressive," this type of MS affects about 15 percent of patients with the neurodegenerative disease.

"There really hasn't been a lot of research or treatment options for patients with this form of MS," said Dr. Kathleen Hawker, assistant professor of neurology, who is heading up the clinical investigation.

UT Southwestern researchers are testing Rituxan – a therapeutic monoclonal antibody approved by the Food and Drug Administration in 1997 for treating some forms of cancer.

"It's an exciting study and the patients are really enthusiastic about this," Dr. Hawker said.

The primary progressive form of MS is characterized by a slow, steady onset, usually beginning with walking difficulties and steadily worsening with motor dysfunctions and increased disability. People with primary progressive MS don't respond as well to traditional drug therapies as patients with other, more common forms of the disease, such as relapsing and remitting MS. Because of this, many people with primary progressive MS have higher incidences of debilitating physical side effects. Many need walkers or wheelchairs.

"Rituxan works on a component of the immune system called B-cells," Dr. Hawker said. "The drug depletes B-cells and has been used to treat other autoimmune diseases such as lupus."

As the lead testing site, UT Southwestern doctors in the MS Program and Clinical Center were involved in developing the protocol, choosing subsequent sites and overseeing the research. There are 61 sites in the Unites States and 11 in Canada currently working on the two-year trial. Total enrollment will be 435 people, with 15 at UT Southwestern.

Patients throughout the region are participating in the study, which still has openings available for those who meet the criteria. People with primary progressive MS usually are in their 40s or 50s, and men and women have an equal risk of developing the disease. Fewer brain lesions are present on a magnetic resonance imaging screening with this form of MS as well, making it more difficult to

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diagnose, Dr. Hawker said.

New patients in the study receive lab work, an electrocardiogram to check their heart, magnetic resonance imaging, spinal tap, and a physical and neurological exam prior to receiving the first dose of the drug.

Patients who can participate in this placebo-controlled study are given infusion treatments that take a full day. Dr. Hawker said positive outcomes for patients during the study would mark a breakthrough for treatment of primary progressive MS. For more information, call 214-648-6449.

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