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NEW STUDY TESTS EFFECTIVENESS OF DRUG FOR MYASTHENIA GRAVIS

DALLAS — March 31, 1997 — Physicians at UT Southwestern Medical Center at Dallas are studying whether intravenous immunoglobulin (IVIG), a drug effective in the treatment of other neurological illnesses, can aid myasthenia gravis patients.

This is the first major drug trial for myasthenia gravis (MG) in several years. IVIG has helped improve the conditions of individuals suffering from peripheral diseases of the nervous system such as Guillain-Barré syndrome. Small studies have indicated IVIG may benefit myasthenia gravis sufferers. But this will be the first blind, placebo-controlled study to investigate the drug's effect on MG patients. Dr. Richard Barohn, associate professor of neurology, and Dr. Gil Wolfe, assistant professor of neurology, at UT Southwestern are serving as the lead investigators for the study.

In myasthenia gravis, the immune system is abnormally activated and antibodies begin attacking neuromuscular receptors. The disease strikes about one person in every 10,000 and occurs in all age groups.

Symptoms include double vision or drooping of eyelids; extreme fatigue; and respiratory and speech difficulties, which result from muscle weakness in the chest and throat. Existing drug therapies, usually using prednisone and other immune suppressants, allow most patients to live independently. But the side effects of prednisone therapy can be serious. In addition, in some individuals the drugs become less effective at preventing further muscle decline and respiratory arrest becomes a risk.

IVIG is a pooled collection of immunoglobulins or antibodies donated from the plasma of 5,000 to 10,000 or more normal donors. The medication needs to be taken intravenously. At the beginning of therapy, an induction dose is given over two to five days. Each infusion takes three to six hours. After the induction dose, maintenance doses are given monthly for a limited period of time. Side effects occur occasionally in some patients who

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take IVIG, though most people seem to tolerate the therapy without difficulty.

IVIG is expensive, costing \$50 to \$100 per gram. If a patient is given 140 grams of IVIG, a typical induction dose, the cost could total \$14,000. Participants in the study will not be charged for the medication.

"We are hopeful that this drug will help MG patients," Barohn said. "It is considerably more expensive than the most common therapy, steroids, but has fewer serious side effects."

Two groups of patients will be enrolled in the study. One set will include individuals who are on a drug called mestinon but have never been on prednisone or other immunosuppressive drugs. The other group will be taking both prednisone and mestinon. All patients must have symptoms of the disease.

The UT Health Science Center in San Antonio, the University of Minnesota Medical School — Minneapolis, Ohio State University College of Medicine and the University of Rochester in New York also will enroll patients in the study, which will be funded through a donation by the Muscular Dystrophy Association.

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