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SIU Med School to Conduct Phase III Clinical Trial of Creatine for Parkinson's Disease *Nutritional Supplement May Slow Progression of Disease*

Southern Illinois University School of Medicine will participate in a large-scale national clinical trial to learn if the nutritional supplement creatine can slow the progression of Parkinson's disease (PD). While creatine is not an approved therapy for PD or any other condition, it is widely thought to improve exercise performance. The potential benefit of creatine for PD was identified by Parkinson's researchers through a new rapid method for screening potential compounds. The trial, which begins today, is sponsored by the National Institutes of Health (NIH).

The double-blind, placebo-controlled, phase III study is one of the largest PD clinical trials to date. SIU School of Medicine is one of 51 medical centers in the United States and Canada that will be recruiting patients as part of an effort to enroll 1720 people with early-stage PD.

“This study is an important step. We are pleased to have so many sites participating in this study, which may help us move more quickly toward developing a therapy that could change the course of this devastating disease,” says Elias A. Zerhouni, M.D., director of the NIH. “The goal is to improve the quality of life for people with Parkinson's for a longer period of time than is possible with existing therapies.” Currently there is no treatment that has been shown to slow the progression of PD.

The trial is the first large study in a series of NIH-sponsored clinical trials called NET-PD (NIH Exploratory Trials in Parkinson's Disease). SIU School of Medicine has been affiliated with the program since 2003. The NIH has organized this large network of sites to allow researchers to work with PD patients over a long period of time, with a goal of finding effective and lasting treatments. NET-PD builds on a developmental research process — from laboratory research to pilot studies in a select group of patients to the definitive phase III trial of effectiveness in people with PD.

“This study is an example of our commitment to Parkinson's research,” said Story C. Landis, Ph.D., director of the National Institute of Neurological Disorders and Stroke (NINDS), the NIH institute leading the study. “We are trying to explore every possible option for reducing the burden of this disease.”

The primary investigator at SIU School of Medicine is Dr. Rodger Elble, Ph.D., chair of neurology and director of SIU's Parkinson Disease and Movement Disorders Clinic. "We are proud to be one of the participating centers in this important and unique step toward finding a cure for Parkinson disease," commented Elble.

PD is a degenerative disorder of the brain in which patients develop symptoms such as progressive tremor, slowness of movements, and stiffness of muscles. It affects at least one million people in the United States. Although certain drugs, such as levodopa, can reduce the symptoms of PD, there are no proven treatments that can slow the progressive deterioration in function.

Creatine is marketed as a nutritional supplement. Studies have suggested that it can improve the function of mitochondria, which produce energy inside cells. It also may act as an antioxidant that prevents damage from compounds that are harmful to cells in the brain. In a mouse model of PD, creatine is able to prevent loss of the cells that are typically affected.

The study will enroll people who have been diagnosed with PD within the past five years and who have been treated for two years or less with levodopa or other drugs that increase the levels of dopamine in the brain. Many of the symptoms of PD result from the loss of dopamine, a neurotransmitter that helps to control movement. Half of the participants will receive creatine and half will receive a placebo. Neither the participants nor their doctors will know which treatment they receive.

The investigators will measure disease progression using standard rating scales that measure quality of life, ability to walk, cognitive function, and the ability to carry out other activities of daily living.

Avicena Group, Inc. will provide the creatine and the placebo for the study.

People interested in participating in this study can obtain information by calling 1-800-352-9424, emailing info@parkinsontrial.org, or visiting <http://www.parkinsontrial.org/> to see the study sites.

The NINDS is a component of the NIH within the Department of Health and Human Services and is the nation's primary supporter of biomedical research on the brain and nervous system. The National Institutes of Health — The Nation's Medical Research Agency — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical, and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

SIU's Parkinson Disease and Movement Disorders Clinic in Springfield provides comprehensive medical, physical and emotional support for individuals with Parkinson Disease, Huntington Disease, Tourette syndrome and other movement disorders. The clinic supports basic and clinical research of Parkinson disease, essential tremor and other movement disorders including clinical trials evaluating medications. For information or appointments, call 217-545-8417 weekdays. To participate in the study, call 217-545-9737 weekdays.

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Note to media – there are 3 other Illinois sites (Chicago area) and one St. Louis site participating. A complete list is available from NIH of SIU offices, listed as contacts.



The National Institute of Neurological Disorders and Stroke
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