

Energy supplement under study for Parkinson's disease

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Whether a supplement used by athletes to boost energy levels and build muscle can slow progression of Parkinson's disease is the focus of a North American study.

Creatine, under study for a number of neurological and neuromuscular diseases such as Lou Gehrig's and muscular dystrophy, may help Parkinson's patients by giving an energy boost to dying cells, says Dr. Kapil D. Sethi, neurologist and director of the Movement Disorders Program at the Medical College of Georgia.

"We think it may help cells that are damaged or overworked," says Dr. Sethi, a site principal investigator on the National Institute of Neurological Disorders and Stroke study. MCG hopes to recruit 45 patients for the study that will enroll 1,720 patients at 51 sites in the United States and Canada.

Mitochondria, the powerhouse for cells, become dysfunctional in the brain, muscle and platelet cells of many patients with Parkinson's disease, Dr. Sethi says. Powerhouse dysfunction is discernible in postmortem brain studies and in muscle biopsies and measures of platelet activity in the living.

"By giving more energy to the cell, you are giving them a safety margin," Dr. Sethi says. "If a cell is dying, it takes another route and that would be surviving."



The goal is to slow progression of a disease that affects about 1 million people in North America. Hallmarks include tremors, rigidity and slowed movement. Late in the disease, the majority of patients also develop dementia and behavior disorders.

Today's therapies – including the gold standard, a synthetic dopamine called levodopa and MAO-B inhibitors that forestall breakdown of dopamine – are geared toward treating symptoms. Dopamine, a neurotransmitter critical to movement, is depleted in Parkinson's. Researchers hope newer therapies, including creatine, can be added to the mix to help slow the disease.

The creatine study will enroll patients who have been on standard therapies from 90 days to two years and follow them for five years. Half the enrollees will get creatine and half placebo. The hope is for at least a 20 percent reduction in disease progression, so that at the end of five years, patients on creatine will look like placebo patients at four years, says Buff Dill, MCG study coordinator.

A number of methods will be used to periodically measure disease progression, including the Unified Parkinson's Disease Rating Scale.

Following disease progression over many years and measuring endpoints such as falling, nursing home placement, dementia and death is the only way to effectively assess treatment for a disease that typically progresses slowly, Dr. Sethi says. In fact, the study may be extended five more years, based on preliminary results and funding, he says.

Those who get creatine may have the added benefit of increased muscle, as is true of athletes, Dr. Sethi says, noting that many patients experience muscle atrophy and weight loss.

Although creatine is available over the counter, he believes Parkinson's



patients will still be interested in the study. "Patients realize that we don't know if it works. They are willing to take the risk of being on placebo for the cause of science and to learn more about the disease," he says, noting the altruistic nature of many of his patients. "They want to beat this disease and if they can't, they want to help somebody else beat it."

Avicena Group, Inc., will provide creatine and placebo for this first large study in a series of National Institutes of Health-sponsored exploratory trials in Parkinson's.

MCG will participate in a similar study of coenzyme Q10, another natural supplement that boosts energy production, later this year. Dr. Sethi, project director of the Parkinson Research Alliance of India, which is working to bring more clinical trials to his homeland, plans to incorporate these supplements into innovative treatment cocktails that will be studied there.

Source: Medical College of Georgia

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