

New delivery method improves efficacy of two common Parkinson's disease medications

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A new delivery method for levodopa/carbidopa, a common dual-drug Parkinson's disease (PD) regimen, significantly improved the duration of the drugs' effectiveness in people with advanced PD, according to research by Mount Sinai School of Medicine. The new method is continuous delivery of an intestinal gel formulation of the therapies, which are traditionally taken orally. The study found that the continuous gel delivery reduced "off" time-when the medicine's effectiveness wears offby an average of nearly two extra hours per day. The gel also improved "on" time without involuntary movements when patients enjoyed a good response, compared to people taking standard levodopa/carbidopa.

The researchers are presenting their findings at the Movement Disorder Society's 16th International Congress of <u>Parkinson's Disease</u> and Movement Disorders being held from June 17-21 in Dublin. the start of the study, the average person had PD for about 11 years and experienced 6.6 hours of "off" time per day. Patients were randomized to receive a continuous infusion of LCIG, delivered

Levodopa is the most effective drug for treating PD, reducing tremors, slowness, stiffness, and walking difficulty, and carbidopa helps prevent nausea and vomiting associated with levodopa. After five to 10 years, however, the duration of its treatment benefits wears off and PD-related symptoms return, representing a major source of disability for patients despite the benefits of the drug. This period of ineffectiveness, which can last six hours or more per day, is known as "off" time.

Researchers led by C. Warren Olanow, MD, Henry P. and Georgette Professor and Chairman Emeritus, Department of Neurology and Director of the Bendheim Parkinson Center at The Mount Sinai Medical Center, performed a double-blind study to explore whether continuous delivery of an intestinal gel form of levodopa/carbidopa could reduce "off" time in people with advanced PD. They found that the levodopa/carbidopa intestinal

gel (LCIG) reduced "off" time by nearly four hours, two hours more than standard oral formulations of levodopa.

"Maintaining a response to oral therapy is a challenge in Parkinson's disease patients, and there is a significant unmet need for a treatment that provides the benefits of the <u>drug</u> without off time or dyskinesia," said Dr. Olanow. "Since it is administered continuously through a pump, LCIG is a promising development that improves outcomes and quality of life in patients with advanced disease."

The research team conducted a 12-week randomized, double-blind trial in 71 PD patients. At the start of the study, the average person had PD for about 11 years and experienced 6.6 hours of "off" time per day. Patients were randomized to receive a continuous infusion of LCIG, delivered through a portable pump connected to a tube implanted in the intestine, plus placebo pills; or placebo gel plus oral <u>levodopa</u>/carbidopa.

Treatment with LCIG was not associated with an increase in troublesome dyskinesia. The most common side effects associated with LCIG treatment involved complications due to inserting the device, abdominal pain, pain during the procedure and nausea.

Provided by The Mount Sinai Hospital



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