

# Clinical trial: Intestinal gel reduces 'off' time in advanced Parkinson's disease

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A levodopa-carbidopa intestinal gel (LCIG) works better than standard oral levodopa-carbidopa in reducing "off" time in patients with advanced Parkinson's disease. That's according to results of the phase three randomized, double-blind clinical trial of LCIG, to be presented as part of the Emerging Science program (formerly known as Late-Breaking Science) at the American Academy of Neurology's 64th Annual Meeting in New Orleans April 21 to April 28, 2012. "Off" time occurs when Parkinson's symptoms like tremor, slowness, stiffness and walking difficulty return as the beneficial effects of oral treatments wear off.

The intestinal gel contains levodopa and carbidopa, two drugs commonly prescribed for Parkinson's, and is infused through a portable pump connected to a tube implanted in the [intestine](#), similar to a feeding tube.

"Off" time was reduced because the infusion of LCIG helps to deliver levodopa-carbidopa continuously, thereby avoiding the fluctuating levels that occur with standard oral levodopa-carbidopa therapy and that are thought to contribute to the development of wearing off," said study author C. Warren Olanow, MD, Professor of Neurology and Neuroscience at the Mount Sinai School of Medicine in New York and a Fellow of the American Academy of Neurology.

In the three-month double-blind trial, 71 participants were randomized to receive either the continuous infusion of LCIG and dummy pills or a dummy intestinal gel and pills that contained levodopa and carbidopa. At the start of the study, the average person had [Parkinson's disease](#) for about 11 years and experienced 6.6 hours of "off" time per day. A total of 93 percent of participants completed the study.

The study found that the continuous LCIG reduced 'off' time by an average of nearly two extra hours per day and improved "on" time without

troublesome movements by an average of two hours per day compared to people taking standard levodopa-carbidopa. Treatment with LCIG was also not associated with an increase in troublesome dyskinesia.

"Less 'off' time for people with Parkinson's means more time during the day in which they can enjoy the benefits of levodopa-carbidopa therapy and experience improved quality of life. We believe that benefits observed with this method of treatment compare favorably with other methods for treatment, such as deep brain stimulation, and avoid the need for an intracranial neurosurgical procedure," said Olanow.

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 American Academy of Neurology

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