Medical Xpress

Gel reduced daily tremors in Parkinson's disease

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(Medical Xpress)—An experimental treatment for Parkinson's disease reduced by nearly two hours on average the period each day when medication failed to control patients' slowness and shaking, according to results from a double-blind, phase III clinical trial published in December 2013, in *Lancet Neurology*.

The study compared AbbVie's levodopa-carbidopa intestinal gel against the same medication in pill form in patients with advanced disease.

The University of Alabama at Birmingham was among the sites for the study, with David G. Standaert, M.D., Ph.D., chair of the UAB Department of Neurology, an author. Led by the Mount Sinai School of Medicine, preliminary results from the study were first presented at the annual meeting of the American Academy of Neurology in April 2012.

Parkinson's disease results from the loss of brain cells that make dopamine, which helps to control movement. As dopamine levels fall, patients experience tremors, muscle stiffness and loss of balance. A commonly prescribed treatment, the levodopa-carbidopa combination works as the body converts levodopa into dopamine and carbidopa escorts levodopa to the right part of the brain. The problem is that patients face hours of uncontrolled slowness, freezing and tremors each day—called "off-time"—as the treatment gets into place or wears off.

One reason for the break in treatment coverage is that it comes in a pill, and pills sit in the stomach for up to six hours waiting for it to empty

into the small intestine. It is only there that levodopa encounters the proteins capable of transporting it into the bloodstream en route to the brain. Thus, researchers envisioned a system that steadily delivers levodopa gel directly into the small intestine through a surgically placed tube, and with the help of a pump worn on the belt.

"The results are very exciting, considering that other recently approved drugs on the market reduce off-time by, at most, just over an hour," said Standaert. "In the study, the gel treatment helped patients who had run out of alternatives with current medications. We believe it may be an important new option for patients with severe Parkinson's, with benefits comparable to more invasive techniques like deep brain stimulation."

Patients using the gel system saw an average reduction in daily off-time of 1.91 hours, and an increase in "on-time" without troublesome dyskinesia of 1.86 hours compared with the pill form. Nearly all subjects experienced at least one side effect, although most were short-lived and moderate.

More information: "Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study." Prof C Warren Olanow MD, Karl Kieburtz MD, et al. *The Lancet Neurology* 20 December 2013. DOI: 10.1016/S1474-4422(13)70293-X

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