Clinical trial shows subcutaneous infusion pump safe, effective for Parkinson's treatment

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An international, multisite Phase III trial, co-led by a University of Cincinnati researcher, has found that a Parkinson's disease medication

delivered through an infusion pump is safe and effective at reducing symptoms for longer periods of time.

These results, published March 15 in the *Lancet Neurology* journal, could lead to additional treatment options for patients with the condition.

Parkinson's symptoms such as tremors, slowness and stiffness are caused by low levels of dopamine in the body. For decades, doctors have treated Parkinson's by giving patients levodopa, the inactive substance in the brain that once converted makes dopamine.

"Levodopa is a replacement strategy. We all make levodopa, but Parkinson's patients make less of it," said Espay, co-principal investigator of the trial.

Espay said oral levodopa is effective and typically helps people regain normal motor function, but its benefits tend to last less than a few hours after a few years, requiring increases in doses or its frequency.

Levodopa is most commonly administered orally, but this trial tested continuous, 24-hour levodopa delivery through a subcutaneous infusion pump. A total of 381 patients with Parkinson's disease in 16 countries enrolled in the trial and were randomized to receive levodopa through the infusion pump or through traditional oral medication.

The researchers found levodopa delivered through the infusion pump was safe and led to almost two hours of day (1.72) of additional "on time," or the time when the medication is working and symptoms are lessened, compared to taking levodopa orally.

Espay said the results of this trial pave the way for this specific infusion pump delivery system to be approved by the Food and Drug Administration and other countries' respective governing bodies.

"Once approved, this will become an important treatment strategy to consider for patients with Parkinson's disease experiencing motor fluctuations not adequately controlled with medication," he said. "Future studies will need to determine the durability of the long-term benefits and whether any safety issues could emerge, as well as how it might compare with deep brain stimulation."

Two additional subcutaneous delivery systems are also expected to be approved this year, Espay said, and researchers are continuing to study how to improve levodopa formulations and delivery to optimize its effect for patients.

"Levodopa delivery systems are expected to continue to improve over time," he said. "This is a thriving area of research for the benefits of our patients."

More information: Alberto J Espay et al, Safety and efficacy of continuous subcutaneous levodopa–carbidopa infusion (ND0612) for Parkinson's disease with motor fluctuations (BouNDless): a phase 3, randomised, double-blind, double-dummy, multicentre trial, *The Lancet Neurology* (2024). DOI: 10.1016/S1474-4422(24)00052-8

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