

Trial Studies New Way to Deliver Parkinson's Medication

5 August 2010, by Keith Herrell

(PhysOrg.com) -- Most medications for Parkinson's disease are taken orally, at certain times of the day. But doctors at UC Health University Hospital are participating in a clinical trial that significantly changes the Parkinson's drug-delivery model.

Parkinson's disease is a chronic, degenerative neurological disorder in which certain dopamine-producing cells in a region of the brain begin to die. When these cells die, neurons in the brain fire erratically, leaving patients less able to direct or control their movements.

Abbott Pharmaceuticals' Levodopa-Carbidopa Intestinal Gel treatment system (referred to as Duodopa in Europe, where it is commercially available) feeds levodopa (the precursor of dopamine) into the upper intestine via a small tube inserted directly into the first part of the small bowel, or duodenum. The medication is suspended as a stable gel from a cassette worn outside the body. The programmable pump allows the patient or physician to adjust the delivery of medication.

The system is in a phase 3 clinical trial, the final step of testing before study results are submitted to the [Food and Drug Administration](#) (FDA) to obtain a New [Drug Application](#). Phase 3 trials are multi-center trials on large patient groups.

"With the way we administer most other Parkinson's medications, the stimulation to [dopamine receptors](#) is given, then taken away, in multiple cycles throughout the day," says UC Health neurologist Alberto Espay, MD, a member of the UC Neuroscience Institute at University Hospital. "With this system, we're basically bathing the patient in dopamine at all times, at a more physiologic rate, eliminating the artificial variability of stimulation that is otherwise inflicted upon the brain."

If found to be safe and effective and approved by the FDA, the system may offer the greatest

potential for patients with advanced stage Parkinson's disease where oral treatments are no longer effective. With Parkinson's, Espay says, there is a wearing-off phenomenon as the disease progresses and intervals between doses need to become progressively shorter to minimize the re-emergence of Parkinson's symptoms.

Espay works in cooperation with UC Health physician Nathan Schmulewitz, MD, who performs the tube insertion procedure at University Hospital. Patients typically are hospitalized for about a week for testing before the procedure and recuperate in the hospital afterward.

Don Truesdale, 46, of Maineville, underwent the procedure at University Hospital in March 2009. He wears the cassette 16 hours a day, taking it off to sleep at night.

"The whole experience at University Hospital was top-notch," he says. "Everyone from the physical therapy assistants all the way up was tremendous."

Provided by University of Cincinnati

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