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Abstract Title: Randomized, double-blind, double-dummy study of continuous infusion of levodopa-carbidopa intestinal gel in patients with advanced Parkinson’s disease: Efficacy and safety

Objective: Assess efficacy, safety, and tolerability of levodopa-carbidopa intestinal gel (LCIG) compared to standard levodopa-carbidopa immediate-release (IR) tablets in patients with advanced Parkinson’s disease (PD).

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Background: Fluctuating blood levels of levodopa may contribute to motor complications in PD. LCIG infusion by intrajejunal percutaneous gastrostomy tube provides more continuous delivery of levodopa than oral levodopa.

Methods: A double-blind, double-dummy trial evaluated efficacy, safety, and tolerability of continuous LCIG during waking hours compared to oral levodopa-carbidopa IR in PD patients with motor complications (NCT00357994). Patients received LCIG infusion + placebo capsules, or encapsulated levodopa-carbidopa IR tablets + placebo gel infusion for 12 weeks. The primary endpoint was change from baseline to Week 12 in “off” time normalized to 16 waking hours. “On” time without troublesome dyskinesia (TD) was a key secondary outcome. Adverse events (AEs) were monitored. ANCOVA was employed, with baseline “off” time and average daily rescue levodopa dose as covariates.

Results: 71 patients were randomized (n=37 LCIG; n=34 IR), and 93% (n=66) completed the trial. Mean PD duration was 10.9 yrs. Baseline mean “off” time and “on” time without TD was 6.6 and 8.3 h/d, respectively. LCIG significantly improved “off” time (LS mean difference = -1.91 hr; P=0.0015) and “on” time without TD (LS mean difference = 1.86 hr, P=0.0059) compared with IR. There was no significant change in “on” time with TD. AEs occurred in 35 (95%) and 34 (100%) patients receiving LCIG and IR, respectively; complication of device insertion (51%), abdominal pain (42%), procedural pain (32%) and nausea (25%) were most common.

Conclusions: LCIG produced clinically meaningful and statistically superior improvements in “off” time over IR, without increasing dyskinesia. AEs were generally related to the placement of intrajejunal tube.

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