Continuous levodopa/carbidopa infusion is considered the optimal delivery route for treating patients with PD and advanced motor fluctuations because it avoids the peaks and troughs associated with oral dosing. However, continuous infusion systems may be surgically invasive, limiting their use in certain patient populations.

NeuroDerm has developed ND0612, a proprietary novel liquid formulation of levodopa/carbidopa delivered by subcutaneous infusion via a belt pump system. ND0612 has been specifically developed to provide a continuous and stable source of levodopa in patients with moderate and advanced PD, while avoiding the surgical risks of intra-intestinal infusion.

Continuous and stable levodopa delivery (24 hours) with ND0612 offers any benefits over waking day infusions (e.g. reduced motor fluctuations).

This Phase 2 study aimed to evaluate whether continuous 24-hour delivery of subcutaneous ND0612 offers practical and clinical benefits over continuous delivery over the waking day (24 hours).

### Methods

**ND0612-006** was an open-label, rater-blind, multicenter, parallel-group, randomized clinical study investigating the efficacy, pharmacokinetics, safety and tolerability of continuous subcutaneous delivery of levodopa/carbidopa (60 mg/mL levodopa and 7.5 mg/mL of carbidopa) delivered by subcutaneous infusion via a belt pump system. ND0612 has been specifically developed to provide a continuous and stable source of levodopa in patients with moderate and advanced PD, while avoiding the surgical risks of intra-intestinal infusion.

### Baseline

38 subjects were enrolled from 11 sites in the United States (N=12), Europe (N=13) and Israel (N=13).

Baseline characteristics are typical of patients with advanced PD who suffer from motor fluctuations despite optimized treatment. Baseline characteristics were comparable between the 2 groups.

### Late-breaking results

In this Phase 2 study both regimens were well tolerated. The 24h infusion significantly reduced daily OFF time while increasing morning ON time and total daily good ON time. Please refer to [Link](#) for the late-breaking efficiency results.

### References


