

Summary: A prospective, multi-center, randomized, open-label study with blinded raters to evaluate the effects of immediate versus delayed switch to Stalevo on motor function and quality of life in patients with Parkinson's disease with end-of-dose wearing off.

Inclusion Criteria:

1. Be aged 30-80 years (inclusive).
2. Be male or female- Female patients must be either not of childbearing potential (defined as post menopausal for at least one year or surgically incapable of bearing children), or must be practicing one or more of the following methods of contraception during the study: intrauterine device or barrier method in combination with spermicide. Use of oral/hormonal contraception alone is not acceptable. Female patients of childbearing potential must have a negative serum pregnancy test immediately prior to study entry.
3. Have a clinical diagnosis of idiopathic Parkinson's disease exhibiting at least 2 or 3 symptoms (rigidity, resting tremor, bradykinesia).
4. Have EODWO as determined by the investigator: EODWO defined as re-emergence of PD symptoms at the end of at least two daily doses of levodopa during the waking hours.
5. Have a Hoehn and Yahr stage less than or equal to 2.5 **measured during the "on-state"**
6. Be taking a stable dose of immediate release carbidopa/levodopa for a period of at least 1 month prior to baseline.
7. Be using any of the following standard formulation carbidopa/levodopa 25/100 doses:
 - ½ tablet,
 - 1 full tablet, and/or
 - 1 ½ tablets.
8. Be capable of satisfying the requirements of the protocol and must be willing and able to give informed consent according to legal requirements.

Exclusion Criteria:

1. Previous or current use of entacapone or tolcapone.
2. History, signs, or symptoms suggesting the diagnosis of secondary or atypical parkinsonism.
3. Unstable Parkinson's disease requiring booster doses or treatment with prn dose of regimens of levodopa.
4. Patients who experience disabling dyskinesia (a score of greater than 2 on UPDRS question #32, or a score of greater than 2 on UPDRS question #33).
5. A Mini Mental State Examination score of less than 26.
6. Patients who are taking carbidopa/levodopa controlled release or extended release formulations (other than at bed time).
7. The following standard carbidopa/levodopa doses and strengths are not permitted:
 - Patients taking immediate release carbidopa/levodopa 10/100 or 25/250
 - Patients taking fewer than 3 or more than 6 daily doses of immediate release carbidopa/levodopa 25/100.
8. Female patients who are pregnant, trying to become pregnant or nursing an infant.
9. Concomitant treatment with MAO-A inhibitors or neuroleptics (**other than quetiapine**), within 60 days prior to the screening visit. **Quetiapine is allowed for the treatment of agitation, anxiety, or insomnia. The total dose should not exceed 50mg/day.**
10. Concomitant illnesses deemed by the investigator to be clinically significant.
11. Patients with a previous history of Neuroleptic Malignant Syndrome and/or non-traumatic rhabdomyolysis.

12. Participated in another trial of an investigational drug/device within the last 30 days prior to study entry.
13. Patients who have a history of poor compliance or are in the Investigator's judgment unlikely to comply with medical regimes or study requirements.

Contact:

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