DUOGLOBE

DUOdopa/Duopa in Patients with Advanced Parkinson's Disease (PD) –a GLobal OBservational Study Evaluating Long-Term Effectiveness (DUOGLOBE)

Clinical Trial Status:
This study is currently recruiting participants

Clinical Trial Principal Investigator:
Dr. James Boyd

Clinical Trial Protocol Description:
This post-marketing observational study is assessing the effectiveness of Levodopa-Carbidopa Intestinal Gel (LCIG) treatment, with product name DUOPA, in advanced PD patients. An observational study is a study in which drugs are prescribed by your physician for their approved purposes, and your physician treats you as they normally would in clinic. This observational study will collect information about the treatment of your PD for research purposes over the course of 36 months.

LCIG has been marketed in other countries for 10+ years, and just recently it was approved for marketing in the US. Data from previous studies have shown a significant reduction in OFF time for those receiving LCIG, as compared to those receiving only the oral levodopa/carbidopa. The main goal of this PMOS is to assess the long-term effectiveness of LCIG/DUOPA in regular clinical care, by specifically collecting information about:

- The long-term effectiveness on OFF time, as seen over 3 years
- Long-term data for motor symptoms, non-motor symptoms, and Quality of Life

Patients who are eligible for LCIG treatment will join this PMOS before they begin their treatment, to provide baseline data. The study will also consist of visits at Day 1 of LCIG treatment, and at months 3 and 6, and every 6 months after that, up to 36 months.

Clinical Trial Eligibility Criteria:
In order to participate, you must meet the following criteria:

- Are eligible for LCIG therapy based on local guidelines
- Have never received LCIG prior to study
- Your physician has made the decision to treat with LCIG before considering participation in this PMOS

You will not be eligible to participate if any of the following criteria apply to you:

- Have had surgical intervention for PD, such as deep brain stimulation (DBS) or cell transplantation
- Have any condition that is included in the contraindications section of the approved LCIG label locally
- Are currently in treatment with apomorphine infusion
- Are participating in an interventional clinical trial at the same time
- Have insufficient language skills or motivation to complete the study questionnaires

Note: this is a partial list of the inclusion and exclusion criteria

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Please contact the Clinical Research Coordinator with any questions.