1.0 Abstract

Title

A post marketing observational study of activities of daily living in advanced Parkinson‘s disease patients with early troublesome motor fluctuations and treated with Duodopa - a multi-country study - MONOTREAT

Keywords

Advanced Parkinson’s disease, Duodopa, levodopa/carbidopa intestinal gel, PEG-J

Rationale and Background

Patients with advanced Parkinson’s disease (PD) experience a range in the severity of their motor fluctuations. The rationale for this post-marketing observational study (PMOS) was to demonstrate the benefits of Duodopa treatment on PD patients entering the advanced stage of the disease whose motor fluctuations had become troublesome on oral therapy.

Research Question and Objectives

The primary objective of this PMOS was to assess the effect of Duodopa treatment on activities of daily living in advanced PD patients. The secondary objectives were to assess:

- The proportion of patients who continue with PEG-J treatment and to understand the primary reason for discontinuing.
- Motor and non-motor symptoms, quality of life and healthcare resource utilization of patients.

Study Design

This PMOS was performed in a multi-country, multi-center approach. There were five target visits: one at baseline (V0), one at hospital discharge (V1), and visits 3, 6 and 12 months after hospital discharge (V2, V3, and V4).

Setting

Participating countries were Austria, Denmark, Germany, Greece, Italy, Netherlands, and Spain.

Subjects and Study Size, Including Dropouts

For 65 patients a baseline visit has been documented. One patient did not fulfill all selection criteria, was lost to follow-up after baseline, and was hence excluded from the main analysis set (MAS). Accordingly, there were 64 patients in the MAS.

Variables and Data Sources

Motor and non-motor symptoms were assessed using the following questionnaires: Unified PD Rating Scale Part II (UPDRS II, activities of daily living), UPDRS Part III (motor examinations), UPDRS Part IV (complications of therapy: items 32, 33, 34 and 39), and Non-motor Symptoms Scale (NMSS). Quality of life was assessed using the PD Quality of life questionnaire (PDQ-8). Healthcare resource utilization of patients was assessed using Healthcare Resource Utilization questions (HCRU).

Results

There was a mean decrease of 5.0 points in the UPDRS II ON score for the MAS after discharge from hospital (V1) compared to baseline (V0). However, the decrease was smaller (1.4 points) 12 months after discharge from hospital (based on V4-LOCF). In the Duodopa group, the mean decrease in UPDRS II ON was 5.1 points at V1 and 1.8 points at V4. Throughout most other parameters assessed, an improvement of symptoms was observed 12 months after hospital discharge as compared to baseline. P-values are presented in an addendum to this report.

Overall, 23 patients (35.9%) stopped treatment or discontinued the PMOS, most often due to the decision of the patient (9 patients, 14.1%) or due to the decision of the investigator due to a medical event (8 patients, 12.5%). Most patients discontinuing Duodopa treatment returned to standard (oral or transdermal) treatment (16 patients).

21 out of 64 patients (32.8%) in the MAS experienced an adverse event, 14 patients (21.9%) had a serious adverse event. 8 patients (12.7%) experienced adverse events that were considered to be related to Duodopa. 7 patients (11.1%) had adverse events which led to the discontinuation of Duodopa treatment.

Discussion

Overall, a decrease in disability was observed in Duodopa patients. For almost all scores, the decrease was considerable at discharge from hospital and slightly smaller 12 months after discharge from hospital.

Marketing Authorization Holder(s)

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Names and Affiliations of Principal Investigators

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