

1.0 Abstract

Title

Health related quality of life in LCIG patients and LCIG eligible patients continuing oral therapy. A multicenter Post Marketing Observational Study for LCIG in Germany and Switzerland – BALANCE

Keywords

LCIG, Parkinson's disease, HRQL.

Rationale and Background

The BALANCE-Study examines the effect of LCIG on Health Related Quality of Life (HRQL) of patients suffering from Parkinson's disease compared to patients staying on standard oral treatment, despite being eligible for LCIG treatment according to the German guideline for PD therapy.

Study Design

Prospective, multi-center, observational, parallel-group study.

Results

137 patients (55.5% male) suffering from Parkinson's disease and being eligible for LCIG therapy were included in the study. 53.3% of the patients decided to receive LCIG treatment and 46.7% decided to continue SoC therapy. Higher Hoehn & Yahr stages were observed in LCIG group. In the LCIG group 92.3% were classified as Hoehn & Yahr stages 3-5 vs. 64.6% in SoC group. Health Related Quality of life deteriorated in the SoC group within 12 months, whereas PDQ-39 mean values in the LCIG group improved (LCIG mean 2.0 SD 12.9 vs. SoC mean -0.6 SD 8.5). Patients reported an improvement on PDQ-39, while SOC patients reported a deterioration. There was no statistically significant difference between groups. Several parameters of treatment effectiveness showed significant improvements in the LCIG group compared to the SoC group. Thus, LCIG patients showed improvements in activities

of daily living after 6 months (UPDRS II), in motor signs (UDPRS III), in significantly less therapy complications (UPDRS IV items 32, 33, 34, 39), non-motor symptoms after 6 and 12 months (NMSS), risk for aspiration (MDT-PD) and in UDysRS ratings after 6 and 12 months. In addition, the clinical global impression of change showed more improvements for LCIG patients after 12 months (CGI-I). From safety perspective, most LCIG patients had adverse events and serious adverse events and the rate of serious adverse events was higher in the LCIG group (83.6%) compared to SoC patients (18.8%).

Discussion

In general, LCIG treatment demonstrated to be a valuable option compared to SoC treatment in advanced PD patients. Despite higher rates of adverse events possibly due to a greater disease impact, most of the patients who decided to initiate LCIG treatment seemed to benefit from the therapy.