Introduction

ND0612 is an investigational drug utilizing the first ever liquid formulation of levodopa/carbidopa (LD/CD) that is designed to be administered continuously subcutaneously by a mini-pump. Clinical studies have shown that ND0612 achieved constant levels\(^1\) of LD in the blood and improved Parkinson’s Disease (PD) symptoms such as OFF time\(^2\). A Human Factors study focusing on the interaction between the user and the device was conducted in order to examine the perception and the usability of TWIN belt-pump, the device used to administer the high-dose regimen of ND0612, by its target population, patients with advanced PD.

Methods

- Study population consisted of 15 pairs of patients with PD, with their partners (spouse or partner). Patients were a typical representation of patients with moderate to severe PD, balanced sample of male/female.
- Training provided to patients: 4 sessions of 90 minutes each, by trained nurses/trainers during which patients were trained on how to set up and operate the pump system.
- Training sessions were followed by a simulated use assessment, during which the participants were expected to carry out the use steps required to deliver the infusion. At the end of sequence, the correct use per the tasks was evaluated.

Characteristics of Participating Patients with Parkinson’s Disease

<table>
<thead>
<tr>
<th>Gender Balance</th>
<th>Age Distribution</th>
<th>Level of Education</th>
<th>Frequency of OFF-periods</th>
<th>Number of Doses of Levodopa taken per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (33%)</td>
<td>60-79 (75%)</td>
<td>College Graduate (40%)</td>
<td>Almost Every Day (50%)</td>
<td>3 doses/day (53%)</td>
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<tr>
<td>Female (67%)</td>
<td>40-59 (25%)</td>
<td>High school (60%)</td>
<td>1-2 Times a Week (45%)</td>
<td>4 doses/day (45%)</td>
</tr>
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</table>

Patients Setting Up the Pump System

Highly Pictorial Patient Guide

Pump System: Mini-Pump and Disposables

Results

- All 15 pairs of patients and their partners were able to assemble and operate the pump following training, demonstrating user-learning ability and overall user satisfaction from the device use.
- Training materials were shown to be effective in aiding PD patients to achieve safe and effective operation of the pump system.
- Despite inherent motor difficulties, 57% of the total task steps were performed by patients with PD unaided by their partner.
- There was no difference in the performance of pairs and their partners where the patient had severe PD compared to pairs where the patient had moderate PD.

No difference in the performance of pairs where the patient had < 2 hrs OFF-Periods daily, compared to pairs where the patient had > 2 hrs OFF-Periods daily.

Conclusion

The ND0612-associated mini-pump was well perceived by patients with PD and their partners. Furthermore, the study demonstrated that, following appropriate training, patients and their partners were able to independently operate the current, clinical-stage devices and pump used by ND0612 in a home setting simulation in a way that assured effective and safe use. New devices in development for the commercial stage are anticipated to increase the patient’s operational independence even further.

ND0612 product candidates offer PD patients a novel, patient-controlled, easy to use solution that achieves constant levels of LD in the blood and improves motor fluctuations that cannot be adequately controlled with oral therapy and might otherwise require surgical intervention.

References

1. N. Giladi, Y. Caraco, T. Gurevich et al., 19th International Congress of Parkinson’s Disease and Movement Disorders. Late-Breaking Abstracts. Stable levodopa plasma levels with ND0612 levodopa/carbidopa for subcutaneous infusion in Parkinson's disease (PD) patients with motor fluctuations.

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