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Impact of ND0612 on patient reported outcomes: A blinded rater study of 2 dosing regimens

Fabrizio Stocchi[1], Werner Poewe[2], Sheila Oren[3], Ryan Case[3], Karl Kieburtz[4], C. Warren Olanow[4]

[1]Institute of Neurology, IRCCS San Raffaele Pisana, Rome, Italy; [2]Medical University Innsbruck, Innsbruck, Austria; [3]NeuroDerm Ltd., Rehovot, Israel; [4]Clintrex, Sarasota, FL, USA

Introduction

- The presence of motor fluctuations and dyskinesia are well-established contributors to disability and poor quality of life in people living with Parkinson's disease (PD).[1,2]
- ND0612 is an investigational drug-device combination that has been designed to deliver liquid levodopa/carbidopa (60/7.5 mg/mL) by subcutaneous infusion through a non-surgical pump system in order to maintain steady, therapeutic levodopa levels and reduce motor complications in PD.[3]
- We have previously reported the primary efficacy results from this phase II study (NCT02577523) which showed that 24h infusion of ND0612 statistically significantly reduced daily OFF-time while increasing morning ON-time and total daily good ON-time. No safety concerns were identified. Infusion site adverse events were common, yet generally well tolerated.[4]

Objective

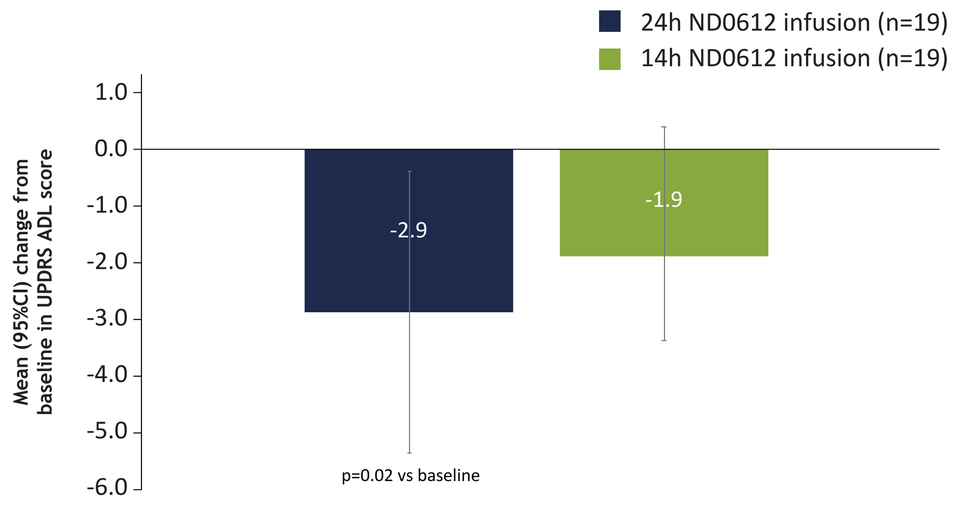
The aim of this analysis of secondary outcomes is to evaluate the efficacy of ND0612 treatment on activities of daily living (ADL) and quality of life (QoL) as self-rated by patients.

Conclusions

- 24 hour, 'round-the-clock' levodopa sc infusion with ND0612 improved patient ratings of ADL, QoL, and overall clinical status ($p<0.05$).
- ND0612 may provide a non-surgical treatment option for continuous levodopa delivery in patients with PD experiencing motor fluctuations.

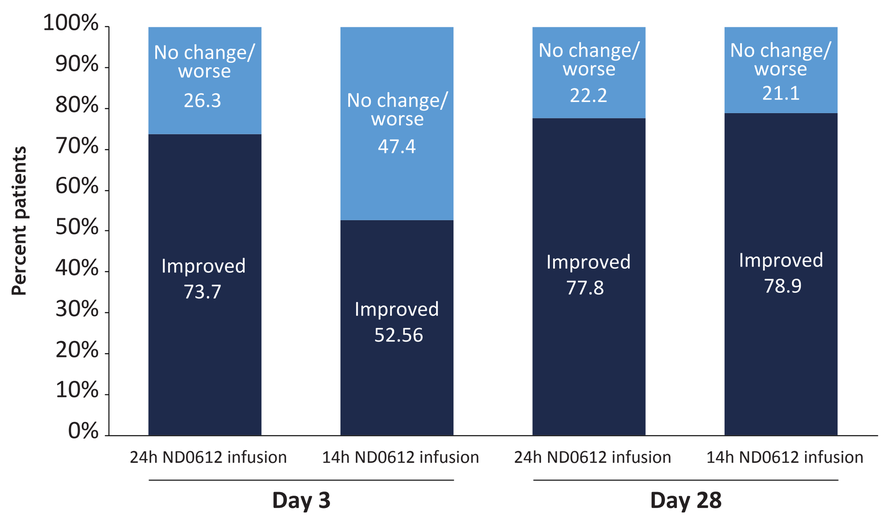
Result 1

Statistically significant improvements (p=0.02) in activities of daily living were seen with the 24h ND0612 regimen



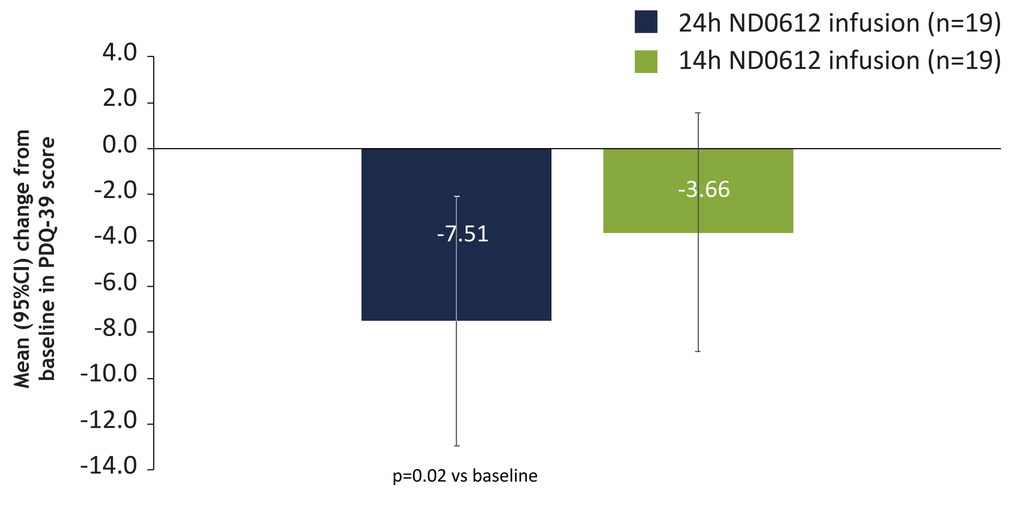
Result 3

Over 70% of patients treated with 24h ND0612 infusion self-reported improvements in their clinical status already at Day 3



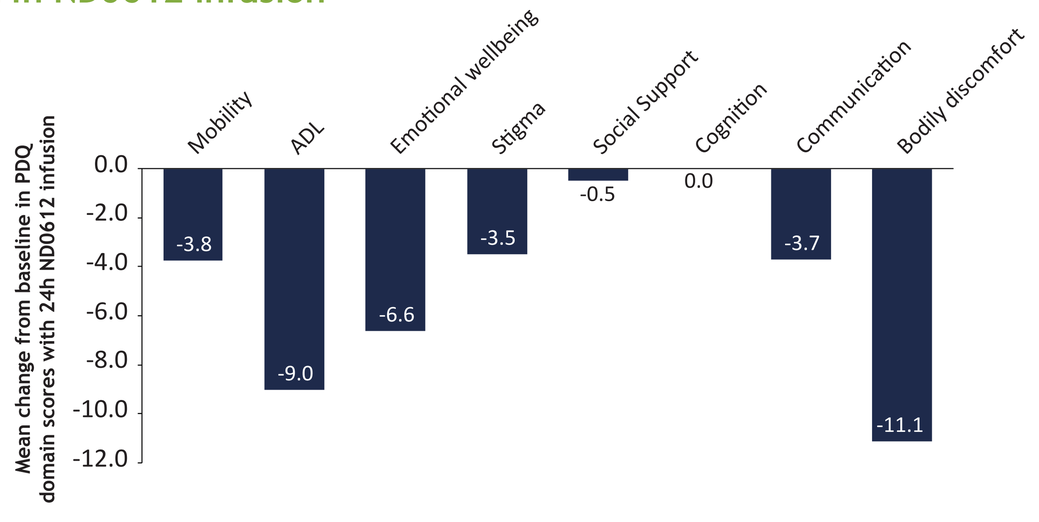
Result 2

Statistically significant (p=0.02) improvement in quality of life with 24h ND0612 infusion



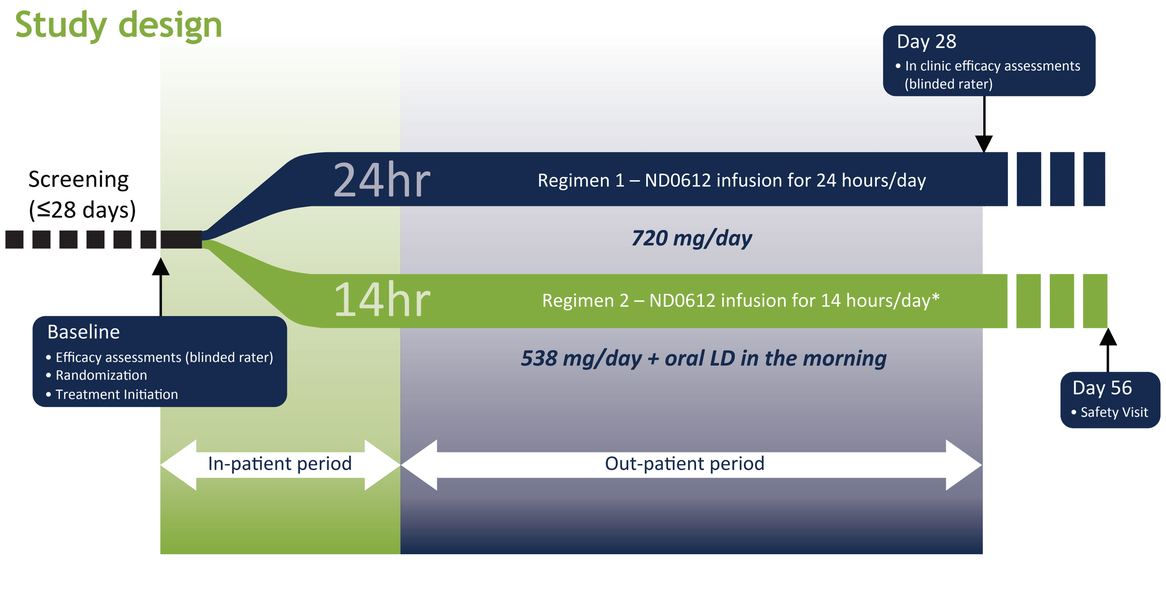
Result 4

6 out of 8 PDQ-39 QoL domains showed improvement following 24h ND0612 infusion



Methods

Study design



- This was a 28-day randomized, parallel-group, open label, blinded-rater study (NCT02577523).
- Male and female (30 – 80 years) patients with a diagnosis of PD and a Hoehn & Yahr stage ≤3 (during ON) were eligible for the study. Patients had to be taking ≥4 levodopa doses per day (≥3 doses/day of IPX-066), have ≥2.5 hours of OFF time per day including predictable and well defined early morning OFF periods, and a 'good' early morning response to levodopa. A total of 38 patients were randomized (1:1) to 2 dosing regimens of ND0612 Supplemental oral LD/CD was used as needed.
- Patient reported outcomes included the UPDRS Part II (ADL) at Day 28 and PD Questionnaire (PDQ-39) at Day 27. In addition, patients self-rated their impression of improvement at Days 3 and 28.

* In this study, the 14 hour waking day dosing regimen was not optimized because it provided a relatively low daily levodopa dose and daily treatment initiation was delayed until a nurse started the pump. A longer daytime regimen of 16 hours ND0612 infusion starting immediately upon waking is under evaluation in the BeyoND study (NCT02726386), which will also evaluate the long-term safety of ND0612.

References

1. Chapuis et al. *Mov Disord* 2005; 20(2): 224-30.
2. Kuhlman et al. *Parkinsonism Relat Disord* 2019.
3. Giladi et al. *Mov Disord*. 2017; 32 (suppl 2).
4. Poewe et al. *Mov Disord* 2018; 33: S92-3.

Disclosures

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