Movement Disorders / Early View

Research Article

A Phase 2a Trial Investigating the Safety and Tolerability of the Novel Cortical Enhancer IRL752 in Parkinson's Disease Dementia

Per Svenningsson MD, PhD ✉, Per Odin MD, PhD, Nil Dizdar MD, PhD, Anders Johansson MD, PhD, Sotirios Grigoriou MD, Panagiota Tsitsi MD, Klas Wictorin MD, PhD ... See all authors

First published:21 March 2020
https://doi.org/10.1002/mds.28020

The IRL752 Collaborators are listed in the Appendix.

Relevant conflicts of interests/financial disclosures: C.S. and J.T. are employees of Integrative Research Laboratories AB. All other authors report no conflicts of interest.

Funding agencies: The study was sponsored and funded by Integrative Research Laboratories AB.

Abstract

Background

IRL752 is a novel small-molecule compound that acts to regioselectively enhance norepinephrine, dopamine, and acetylcholine neurotransmission in the cerebral cortex.

Objective

The primary objective of the trial was to investigate the safety and tolerability of IRL752 in patients with Parkinson's disease and dementia.

Methods

Patients with Parkinson's disease and dementia were randomized to IRL752 or placebo treatment (3:1 ratio) for 28 days. The study drug was given as an adjunct treatment to the patients' regular stable antiparkinsonian medication. Dosing was individually titrated for 14 days after which the dose was kept stable for an additional 14 days.

Results

A total of 32 patients were randomized to treatment, and 29 patients completed the 4-week treatment. Adverse events were generally mild and transient and were mostly reported during the dose titration phase. There were 2 serious adverse events, and none of them were related to the experimental treatment. The average dose achieved in the stable dose phase was 600 mg daily, yielding a 2-hour postdose plasma concentration of

about 4 μM on day 28. Exploratory assessment of secondary outcomes indicated efficacy for symptoms and signs known to be poorly responsive to levodopa.

Conclusions

IRL752 appears to be safe and well tolerated for a 4-week treatment in patients with Parkinson's disease and dementia. © 2020 International Parkinson and Movement Disorder Society

Supporting Information

Filename	Description
MDS_28020-sup-0001-Supinfo.docx Word 2007 document , 41.6 KB	**Supplementary Figure 1** Mean absolute score change with 95% confidence intervals from baseline for cardinal motor features of Parkinson's disease in IRL752 treated patients completing the trial (n = 23) as assessed with UPDRS. For constructs of the four domains se description in Table 3 . **Supplementary Table 1.** Summary statistics for plasma IRL752 concentrations at Day 14 and 28 of treatment.

Please note: The publisher is not responsible for the content or functionality of any supporting information supplied by the authors. Any queries (other than missing content) should be directed to the corresponding author for the article.

About Wiley Online Library

Privacy Policy
Terms of Use
Cookies
Accessibility

Help & Support

Contact Us

Opportunities

Subscription Agents
Advertisers & Corporate Partners