Neurodegenerative



Disorders Research Neurodegenerative Disorders Research Pty Ltd

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Aim

To determine the safety of Dimebon and evaluate its effect on cognitive abilities in subjects with diagnosed Huntington's disease (HD)

Phase III

Randomized, Double-Blind, Placebo-Controlled Safety and Efficacy Study

Hypothesis

Dimebon, a mitochondrial stabilizing agent with cholinesterase and N-methyl-D-aspartate (NMDA) receptor effects, improves cognition and global function, including acts of daily living in patients with HD.

Co-primary objectives:

- To determine effect on cognition as measured by the mini-mental state exam (MMSE).
- To determine the effect on global function using the Clinicians Interview-Based Impression of Change, plus caregiver input (CIBIC-plus).

TGA Trial 2009/459

Funding

- Medivation Inc
- Pfizer Inc
- Huntington Study Group
- European Huntington's Disease Network
- York Neuroscience Discovery Inc

Criteria

To be eligible for the Horizon Study participants must:

- be at least 30 years old or more,
- be able to provide informed consent,
- have clinical features of mild to moderate HD,
- have difficulty with cognitive abilities,
- have a caregiver for at least 3 hrs/day, 5 days/week,
- be able to take oral medication, and
- not be pregnant, lactating or become pregnant.

Status

Study completed

Ethics approval

Bellberry Human Research Ethics Committee (A91/09)

Contact

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