Drug-Drug interaction study in HV

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28697

Source
NTR

Brief title
CHDR1840

Health condition

Parkinson's disease.

Sponsors and support

Primary sponsor: Denali Therapeutics, Inc
Source(s) of monetary or material Support: Denali Therapeutics, Inc

Intervention

Outcome measures

Primary outcome

The primary objectives of the study are to estimate the following:

• The measurable maximum plasma concentration (Cmax) of DNL151 in the presence and absence of ITZ

• The area under the concentration-time curve (AUC) of DNL151 in the presence and absence of ITZ

• The terminal half-life of DNL151 in the presence and absence of ITZ

Secondary outcome

Safety and tolerability of administration of DNL151 alone and in the presence of ITZ

Study description

Background summary

This was a single center study, all healthy volunteers were recruited in the Netherlands

Study objective

LRRK2 kinase inhibitors represent a new class of therapeutics with potential to address the underlying biology of Parkinson’s disease. LRRK2 activity is linked to a central mechanisms of Parkinson’s disease pathology through its role in lysosomal function. DNL151 is an inhibitor of LRRK2 kinase, a genetically validated target, and is expected to impede the underlying disease process. Therefore, DNL151 may prevent or slow the progression of motor and nonmotor disabilities that define the progression of Parkinson’s disease.

Study design

Up to follow-up phase

Intervention

DNL151
Itraconazole

Contacts

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Eligibility criteria

Inclusion criteria

Subjects enrolled in the study were required to meet all the following criteria for study entry:
• Men or women of any race, between 18 and 50 years of age, inclusive, at screening
• BMI between 18.0 and 31.0 kg/m2, inclusive, and a body weight of at least 50.0 kg at Screening
• In good health determined by no clinically significant findings from medical history, physical examination, and vital sign measurements
• All clinical laboratory tests must be within normal limits or no clinically significant abnormalities

Exclusion criteria

Subjects who met any of the following criteria were excluded from study entry:
• History of clinically significant hematological, renal, pancreatic, gastrointestinal, hepatic, cardiovascular, metabolic, endocrine, immunological, allergic disease, or other major disorders as determined by the investigator
• Abnormal vital signs at screening
• Clinically significant neurologic disorder
• Evidence of ANY hepatic impairment
• Clinically significant ECG abnormality at screening
• History of clinically significant congestive heart failure.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2018
Enrollment:	16
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7350
NTR-old	NTR7559
Other	Stichting BEBO : CHDR1840

Study results

Summary results
No