SAD and food-effect study of YTX-7739

No registrations found.

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

Summary

ID

NL-OMON21001

Source
Nationaal Trial Register

Brief title
CHDR1911

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: Yumanity Therapeutics
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

Safety and tolerability, PK and PD

Secondary outcome

NA

Study description

Background summary

YTX-7739 is a novel, orally active inhibitor of SCD enzymatic activity.
Here, we aim to explore the safety, tolerability, pharmacokinetic and pharmacodynamic properties of YTX-7739 in healthy adult volunteers (part A) as a prelude to further study this molecule as a potential disease modifying therapy for Parkinson’s disease and related neurological disorders. In part B, we aim to assess the effect of food on the pharmacokinetics of YTX-7739.

Study objective

Here, we aim to explore the safety, tolerability, pharmacokinetic and pharmacodynamic properties of YTX-7739 in healthy adult volunteers (part A) as a prelude to further study this molecule as a potential therapy for Parkinson’s disease. In part B, we aim to assess the effect of food on the pharmacokinetics of YTX-7739.

Study design

Screening, Day -1, Day 1, Day 2, Day 5, Day 7, Follow Up by phone.

Intervention

YTX-7739 10mg, 30mg, 100mg, 250mg, 500mg and placebo

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy male and female subjects 18-45 years of age, inclusive. Healthy status is defined by absence of evidence of any active acute or chronic disease or illness following a detailed medical and surgical history, a complete physical examination including vital signs, 12-lead ECG, hematology, blood chemistry and urinalysis;
2. Body mass index (BMI) between 18-35 kg/m2, inclusive, and with a minimum weight of 50kg and maximum weight of 120kg;
3. Evidence of a personally signed, dated and witnessed informed consent document indicating that the subject has been informed of all pertinent aspects of the study;
4. Able and willing to give written informed consent and to comply with all study restrictions.

Exclusion criteria

2. Clinically significant findings, as judged by the investigator, as determined by medical history taking, physical examination, ECG and vital signs;
3. Subjects with a borderline QTcF of > 450 ms for males and > 470 ms for females at screening or a history of long QT syndrome;
4. Hemodynamic status at screening: systolic blood pressure <100 or >160 mmHg, diastolic blood pressure <60 or >95 mmHg or heart rate <45 or >100 bpm
5. Any current, clinically significant, known medical condition, as judged by the investigator;
6. Pregnant, lactating or breast-feeding women;
7. Have a urine drug screen detecting illicit drug(s) of abuse (morphine, benzodiazepines, cocaine, amphetamine, THC) or positive alcohol breath test at screening.
8. Positive Hepatitis B surface antigen (HBsAg), Hepatitis C antibody (HCV Ab) or human immunodeficiency virus antibody (HIV Ab) at screening;
10. History or clinical evidence of alcoholism or drug abuse;
15. Subjects of childbearing potential who are unwilling or unable to use a highly effective method of barrier contraception for the duration of the study and for at least 90 days after their last dose of study treatment.
16. All males who are unwilling to practice effective contraception and abstain from sperm donation during the study and who are not willing and able to continue contraception and abstain from sperm donation for at least 90 days after their last dose of study treatment.
17. Any confirmed significant allergic reactions (urticaria or anaphylaxis) against any drug, or multiple drug allergies (non-active hay fever is acceptable).

Study design

Design

Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2019
Enrollment:	48
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	27-12-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49863
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8258
CCMO	NL71070.056.19
OMON	NL-OMON49863

Study results