SAD and MAD of NT-0167 in healthy volunteers

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23660

Source
NTR

Brief title
CHDR1925/NT-0167-P001

Health condition

Inflammatory disorders; Neurodegenerative diseases

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Tolerability / safety endpoints
• Treatment-emergent (serious) adverse events ((S)AEs)
• Clinical laboratory tests
o Haematology
o Chemistry

o Urinalysis
o Coagulation
o Thyroid function tests
• Vital signs
o Pulse Rate (bpm)
o Systolic blood pressure (mmHg)
o Diastolic blood pressure (mmHg)
o Respiratory Rate (breaths/min)
• Electrocardiogram (ECG)
o Heart Rate (HR) (bpm), PR-, QRS-, and QTcF-intervals
o Morphological abnormalities
• Holter ECG (not in Food cohort)
• Physical examination
• Weight (only during MAD cohorts)

Secondary outcome

Pharmacokinetic endpoints
Pharmacodynamic endpoints
The effect of food on the PK profile and tolerability of NT-0167

Study description

Background summary

This project is testing the safety, tolerability, pharmacokinetics (PK, the amount of study drug in your blood) and pharmacodynamics (PD, how the study drug affects your body) of both single and multiple oral doses of a
new drug called NT-0167.
Up to eighty (80) healthy men or women of non-child-bearing potential (WNCBP), aged between 18-55 will be enrolled in this study in up to six SAD and up to four MAD cohorts comprising 8 subjects each.
This study will enroll approximately 80 participants, in two parts:
Part A: will involve a single ascending (increasing) dose (SAD) where approximately 48 participants (6 groups of 8) will be randomised (assigned randomly, like flipping a coin) to receive a single dose of the study drug or
placebo. The placebo will look the same as the study drug but will not contain any medicine.
Part A (Food Effect): One group from Part A will return for an additional dose to determine the effect of food on the pharmacokinetics (PK) of the study drug.
Part B: will involve a multiple ascending (increasing) dose (MAD) where approximately 32 participants (4 groups of 8) will receive one dose of the study drug or placebo daily for 14 consecutive days (14 doses in
total).

Study objective

Primary objective:
- To evaluate the safety and tolerability of NT-0167 in healthy volunteers

Secondary:
- To evaluate the pharmacokinetic (PK) profile of NT-0167 in healthy volunteers after the administration of single ascending (SAD)
and multiple ascending doses (MAD);
- To evaluate the pharmacodynamic (PD) properties of NT-0167 in healthy volunteers after single ascending and multiple ascending
doses based on ex vivo inflammasome challenges;
- To evaluate the effect of food on the PK profile and tolerability of NT-0167 after a single dose administration.

Study design

-42 days till EOS

Intervention

NT-0167

Contacts

Public
Centre for Human Drug Research
M. Moerland

+31 71 5246 400
Scientific
Centre for Human Drug Research
M. Moerland

+31 71 5246 400

Eligibility criteria

Inclusion criteria

Eligible subjects must meet all of the following inclusion criteria at screening:

1. Signed informed consent and willing and able to comply with the study protocol;
2. Healthy men or women of non-child bearing potential (WONCBP), 18 to 55 years of age (inclusive) at screening. The health status is verified by absence of evidence of any clinically significant active or uncontrolled
chronic disease following a detailed medical history, a complete physical examination including vital signs, laboratory measurements, and 12-lead ECG;
3. Female subjects must be of non-childbearing potential in accordance with one of the following definitions:
• Surgically sterile (by hysterectomy and/or bilateral oophorectomy and/or bilateral salpingectomy) as documented
by a surgical report or by ultrasound, or
• Post-menopausal (age-appropriate spontaneous amenorrhoea for ≥12 months and follicle-stimulating hormone (FSH) ≥ 40 IU/mL together with the absence of oral contraceptive use for >12 months);
4. Male volunteers agree to use barrier protection when they engage in sexual relations with women of childbearing potential (WOCBP) or lactating women for the duration of their participation in the study and until 90 days after EOS.
5. Body mass index (BMI) between 18 and 32 kg/m2, inclusive, and with a minimum bodyweight of 50 kg;
6. Has the ability to communicate well with the Investigator in the Dutch language and willing to comply with the study restrictions.
7. Have the intention to be reachable by mobile phone or e-mail during the whole study period

Exclusion criteria

Eligible subjects must not meet any of the following exclusion criteria at screening or pre-dose:
1. Lactating females;
2. Female volunteers with a positive pregnancy test at screening or baseline prior to IMP administration;
3. Evidence (including symptoms, physical signs, and/or laboratory values) of any active or chronic disease or condition that could interfere with, or for which the treatment might interfere with, the conduct of the study, or that would pose an unacceptable risk to the subject in the opinion of the investigator;
4. Any confirmed or suspected disease or condition associated with immune system impairment, including auto-immune diseases, HIV, asplenia or recurrent severe infections.
5. Use of chronic (more than 14 days) immunosuppressant or immunomodulatory drugs within the 6 months prior to IMP administration, or isolated (non-chronic) use within 30 days prior to
IMP administration;
6. Any history of severe allergic reaction(s);
7. Any confirmed significant drug hypersensitivity reactions (including skin reactions or anaphylaxis), or known allergies (non-active hay fever is acceptable);
8. History of clinically significant systemic disorders including haematological, renal,

endocrine, gastrointestinal, hepatic, cardiovascular, pulmonary, dermatological and neurological
disorders, or other conditions which could interfere with the interpretation of the study results or compromise the health of the volunteers;
9. Any history of psychiatric condition that may affect participation in the study or preclude compliance with the protocol;
10. Receipt of any vaccination, other than an influenza vaccine, within 3 months of IMP administration.
11. Participation in an investigational drug, vaccine or device study within 3 months prior to first dosing or plans to participant in other investigational drug, vaccine or device research during the study period.
12. Any nutrients known to modulate CYP enzymes activity (e.g., grapefruit or Seville orange containing products or quinine containing drinks (tonic water or bitter lemon)) will not be permitted from 5 days before dosing until the final PK sample is collected;
13. Donation (or loss) of whole blood of 400 ml or more during the 12 weeks prior to IMP administration;
14. Donation of plasma or platelets during the 8 weeks prior to IMP administration;
15. Any other known factor, condition, or disease that, in the opinion of the Investigator, might interfere with treatment compliance, study conduct or interpretation of the results, or may compromise volunteer safety.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	31-01-2020
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion
Date: 13-08-2020
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49667
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8833
CCMO	NL72337.056.19
OMON	NL-OMON49667

Study results

Summary results
N.A.