A Randomized, Double-Blind, Placebo-Controlled, Phase 1, Single and Multiple Ascending Dose Study to Assess the Safety, Pharmacokinetics, Pharmacodynamics, and Food Effect of THB001 in Healthy Subjects

Gepubliceerd: 01-03-2021 Laatst bijgewerkt: 15-05-2024

Assess the safety and tolerability of single and multiple ascending doses of THB001 in addition to the effects of food in healthy volunteers.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21075

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Preliminary safety study, first in human.

Ondersteuning

Primaire sponsor: Third Harmonic Bio.
Overige ondersteuning: Third Harmonic Bio.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Safety and tolerability parameters for THB001 including: physical examination, AEs, clinical laboratory values, vital signs and ECGs. PK parameters for THB001

Toelichting onderzoek

Achtergrond van het onderzoek

This is a first-in-human study of THB001 conducted as a single ascending dose (SAD), food effect, and multiple ascending dose (MAD) evaluation of safety, tolerability, and pharmacokinetics in healthy volunteers

Doel van het onderzoek

Assess the safety and tolerability of single and multiple ascending doses of THB001 in addition to the effects of food in healthy volunteers.

Onderzoeksopzet

Screening up to -28 days, treatment period up to 17 days and a follow-up period through 77 days

Onderzoeksproduct en/of interventie

THB001 or placebo

Contactpersonen

Publiek

Third Harmonic Bio (Sponsor) / QPS, Groningen (CRO)
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects must understand the nature of the study and must provide signed and dated written informed consent in accordance with local regulations before the conduct of any study-related procedures.

Healthy as determined by the Investigator, based on a medical evaluation including medical history, physical examination, laboratory tests and ECG recording.

Men and women aged 18-65 years (inclusive) who meet all entry criteria.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A history or presence of cancer or of a clinically significant hepatic, biliary, renal, gastrointestinal, cardiovascular, endocrine, pulmonary, ophthalmologic, immunologic, hematologic, dermatologic, or neurologic abnormality.

Evidence or history of anemia, thrombocytopenia, or leukopenia.

Use of any prescription or non-prescription drugs (excluding paracetamol), antacids, vitamins, herbal, and dietary supplements (including St John’s Wort) within 14 days (or 28 days if the drug is a potential hepatic enzyme inducer) or 5 half-lives (whichever is longer) prior to the first dose of study medication, unless in the opinion of the Investigator and Medical Monitor the medication will not interfere with the study procedures or compromise subject safety.

A positive pregnancy test (at Screening or on Day -1 of the (first) treatment period) or lactation.

A history or presence of any disease, condition, or surgery likely to affect drug absorption, distribution, metabolism, or excretion.

A clinically significant abnormality on physical examination, neurological examination, ECG, or laboratory evaluations at Screening or between Screening and (first) dose administration.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-03-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	01-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50828

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9309
CCMO	NL76587.056.21
OMON	NL-OMON50828

Resultaten