Single Ascending Dose Study of ALKS 6610 in healthy adults

Gepubliceerd: 29-01-2020 Laatst bijgewerkt: 15-05-2024

The objective of the study is to evaluate safety, tolerability, and pharmacokinetics (PK) of ALKS 6610 after single ascending oral doses in healthy adult subjects.

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

Samenvatting

ID

NL-OMON20667

Bron
Nationaal Trial Register

Verkorte titel
CHDR1921

Aandoening

Single Ascending Dose Study

Ondersteuning

Primaire sponsor: Alkermes, Inc.
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tolerability / Safety Endpoints
Pharmacokinetic Endpoints

Toelichting onderzoek

Achtergrond van het onderzoek

Subjects will be recruited in The Netherlands to participate in a Single Ascending Dose Study of ALKS 6610 in healthy adults. The study results may be used to support further clinical development of ALKS 6610.

Doel van het onderzoek

The objective of the study is to evaluate safety, tolerability, and pharmacokinetics (PK) of ALKS 6610 after single ascending oral doses in healthy adult subjects.

Onderzoeksopzet

Baseline till EOS

Onderzoeksproduct en/of interventie

ALKS 6610 or placebo

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Signed informed consent prior to any study-mandated procedure
2. Ability to communicate well with the Investigator in the Dutch language and willing to follow the procedures and comply with study restrictions as outlined in the protocol
3. Male or female age ≥18 years and ≤60 years old at the time of informed consent
4. Body mass index (BMI) ≥18 and <30 kg/m2 at Screening

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinically significant illness or disease within 8 weeks of dosing, or any clinically abnormal symptom or organ impairment, found by medical history, physical examinations, vital signs, electrocardiogram (ECG) finding, or either abnormal laboratory values or laboratory test results at Screening or Baseline
2. Females who are breastfeeding or pregnant at Screening or Baseline
3. Females of childbearing potential. NOTE: All females will be considered to be of childbearing potential unless they are postmenopausal or have been sterilized surgically
4. A prolonged QT/QTc interval (QTcF >450 ms in males, and QTcF >470 ms in females) demonstrated on ECG at Screening or Baseline
5. History of clinically significant arrhythmia or uncontrolled arrhythmia
6. Positive Hepatitis A antibodies (HAV IgM), Hepatitis B surface antigen (HBsAg), Hepatitis B antibodies (Anti-HBc), Hepatitis C antibodies (HCV Ab), or human immunodeficiency virus antibody (HIV Ab) at Screening
7. Use of nicotine containing products within 2 weeks before the first dose of study drug (Day 1)
8. Use of prescription and non-prescription medications, herbal and nutritional supplements within 2 weeks prior to dosing or 5 half-lives, whichever is longer.
9. Any history of lifetime suicidal ideation or behaviour, confirmed by a Columbia Suicide Severity Rating Scale (C-SSRS) response of “Yes” to questions 4 or 5 at Screening
10. Currently enrolled in another clinical study, used any investigational drug or device within 3 months prior to dosing, or having participated in more than 4 investigational drug studies within 1 year prior to Screening
11. Additional criteria may apply

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-02-2020
Aantal proefpersonen:	56
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
NA

Ethische beoordeling

Positief advies

Datum:	29-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50062
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8337
CCMO	NL71886.056.19
OMON	NL-OMON50062

Resultaten

Samenvatting resultaten
NA