Study investigating safety, tolerability, PK and PD of KCP506

Gepubliceerd: 06-07-2021 Laatst bijgewerkt: 15-05-2024

The purpose of this study is to investigate how safe the new compound KCP506 is and how well it is tolerated when it is administered to healthy volunteers. It will also be investigated how quickly and to what extent KCP506 is absorbed and eliminated...

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

Samenvatting

ID

NL-OMON28854

Bron
NTR

Verkorte titel
CHDR2034 / KCP506-101

Aandoening

Chronic pain

Ondersteuning

Primaire sponsor: Kineta Chronic Pain, LLC
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• To evaluate the safety and tolerability of KCP506 in healthy adults, following a single intravenous (iv) or subcutaneous (sc) injection at

escalating dose levels
• To evaluate the safety and tolerability of KCP506 in healthy adults, following multiple iv or sc injections at escalating dose levels

Toelichting onderzoek

Achtergrond van het onderzoek

KCP506 is a first-in-class analgesic compound and act as an inhibitor of the α9α10 nicotinic acetylcholine receptor (nAChR), a genetically validated molecular target for chronic neuropathic pain.

This is a 3-part, multi-center study in 108 healthy subjects. The study consists of 3 parts: a single ascending dose (SAD) part A, multiple ascending dose (MAD) part B and a pilot pharmacodynamic (PD) study part C.

This study will provide an assessment of the safety, tolerability, and PK of KCP506 after iv and sc administration of ascending single and multiple doses to healthy male and female subjects, as well as an assessment of the PD of KCP506 after iv administration of a single dose in healthy male subjects.

Doel van het onderzoek

The purpose of this study is to investigate how safe the new compound KCP506 is and how well it is tolerated when it is administered to
healthy volunteers. It will also be investigated how quickly and to what extent KCP506 is absorbed and eliminated from the body.
KCP506 has not been administered to humans before. It has been previously tested in the laboratory and on
animals. KCP506 will be tested at various dose levels.

Onderzoeksopzet

-42 Days (Screening) till EOS

Onderzoeksproduct en/of interventie

KCP506 or placebo

Contactpersonen

Publiek

Centre for Human Drug Research
G. J. Groeneveld

+31 71 5246 400

Wetenschappelijk

Centre for Human Drug Research
G. J. Groeneveld

+31 71 5246 400

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Gender: male (all parts) or female (Parts A and B only)
Age: 18 to 55 years, inclusive, at screening
Weight: 50 to 105 kg, inclusive
Body mass index: 18.0 to 30.0 kg/m2, inclusive
Status: healthy subjects

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous participation in the current study, except subjects in Part C may have participated in Parts A or B,
provided they have not received a dose of KCP506 in the 3 months prior to Part C dosing.
2. Employee of PRA, CHDR or the Sponsor.
3. History of relevant drug and/or food allergies, per the Investigator’s assessment.
4. Using tobacco products within 60 days prior to first drug administration
5. History of alcohol abuse or drug addiction (including cannabis products), per the Investigator’s assessment.
6. Positive drug and/or alcohol screen (opiates, methadone, cocaine, amphetamines [including ecstasy], cannabinoids, barbiturates, benzodiazepines, tricyclic antidepressants, nicotine [cotinine – Parts A and B only]. and alcohol) at screening or first admission to the clinical research center. Tests may be repeated once at screening and once at admission in case of a suspected false positive result.
7. Average intake of more than 24 units of alcohol per week (1 unit of alcohol equals

approximately 250 mL of beer, 100 mL of wine, or 35 mL of spirits).
8. Positive screen for hepatitis B surface antigen (HBsAg), antihepatitis C virus (HCV) antibodies, or antihuman immunodeficiency virus (HIV) 1 and 2 antibodies.
9. Participation in a drug study within 60 days (Parts A and B) or 90 days (Part C) or 5 drug elimination half-lives, whichever is longer) prior to the first drug administration in the current study. Participation in more than 3 other drug studies in the 10 months prior to the first drug administration in the current study.
10. Donation or loss of more than 100 mL of blood within 60 days prior to the first drug administration. Donation or loss of more than 1.5 liters of blood (for male subjects)/more than 1.0 liters of blood (for female subjects) in the 10 months prior to the first drug administration in the current study.
11. Significant and/or acute illness within 5 days prior to the first drug administration that may impact safety assessments or be consistent with COVID-19 infection, in the opinion of the Investigator.
12. Unsuitable veins for infusion or blood sampling.
13. Close contact with persons diagnosed with COVID-19 within 14 days prior to screening.
14. Positive nasopharyngeal PCR or rapid antigen test for SARS-CoV-2 on Day -1.
15. Receipt of a vaccine within 14 days prior to the first study drug administration (Parts A and B) or either study drug administration (Part C).
In addition, a subject who meets any of the following exclusion criteria will not be eligible for inclusion in Part C of the study:
16. Any confirmed significant allergic reactions (urticaria or anaphylaxis) after previous exposure to capsaicin.
17. Subject indicating intolerable pain after capsaicin administration at screening.
18. Wide-spread tattoos or scarring on the volar forearms preventing proper assessment of secondary mechanical allodynia.
19. No secondary mechanical allodynia induced in subject (area of secondary mechanical allodynia = 0 mm2) at screening.
20. Any current, clinically significant, known medical condition that would affect sensitivity to cold (such as atherosclerosis, Raynaud’s disease, urticaria, hypothyroidism) or pain (ie, disease that causes pain, hypesthesia, hyperalgesia, allodynia, paranesthesia, neuropathy).
21. Subjects who, at screening, indicate pain tests to be intolerable or who achieve tolerance at >80% of maximum input intensity for cold and electrical pain tests.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-10-2020
Aantal proefpersonen:	108
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	06-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55203
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9581
CCMO	NL74314.056.20

Register	ID
OMON	NL-OMON55203

Resultaten

Samenvatting resultaten
N.A.