Safety, tolerability, pharmacokinetic (PK) and pharmacodynamic (PD) study with ENX-201

Gepubliceerd: 11-03-2019 Laatst bijgewerkt: 18-08-2022

A relationship exists between a pharmacologic effect of ENX-201 and the plasma concentration

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

Samenvatting

ID

NL-OMON23997

Bron
NTR

Verkorte titel
ENX-201-CR-001

Aandoening

Multiple Sclerosis (relapses)

Ondersteuning

Primaire sponsor: EnhanX Biopharm Inc.
Overige ondersteuning: EnhanX Biopharm Inc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pharmacokinetics in plasma of intravenously administered ENX-201 in terms of Cmax,

Volume of distribution, half-life (T1/2), area under the plasma concentration-time curve (AUC), Clearance (CL)

Toelichting onderzoek

Achtergrond van het onderzoek

In this human volunteers study, the aim is to assess the safety, pharmacokinetics and pharmacodynamics of ENX-201 in a randomized, double-blind, placebo- and active comparator- controlled 3-way crossover study in 12 healthy subjects.

Doel van het onderzoek

A relationship exists between a pharmacologic effect of ENX-201 and the plasma concentration

Onderzoeksopzet

-2h, -15m, 0, 15m, 30m, 1h, 2h, 4h, 6h, 8h, 12h, 24h, 30h, 48h, 72h

Onderzoeksproduct en/of interventie

ENX-201 300mg, once, IV infusion in 5% dextrose/ Methylprednisolone hemisuccinate 300mg, once, IV infusion in 5% dextrose/ Placebo, once, IV infusion of 5% dextrose

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy male and female volunteers, who are able to understand and follow study instructions, age between 18 and 60 years (inclusive), and weight within normal range (body mass index within 18 to 29.9 kg/m2) and at least 50 kg.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Demonstrating excess in xanthine consumption (more than 5 cups of coffee or equivalent per day); More than moderate alcohol consumption or a history of alcohol abuse; drug abuse; consumption of furanocoumarin containing citrus fruits within 7 days of first dosing; Consumption of quinine-containing drinks within 7 days of first dosing; Use of any medications other than highly effective anti-conceptive medicines, vitamins, mineral, herbal and dietary supplements within 21 days of first dosing.; Vaccinations within 3 months prior to screening; Demonstrating any active physical or psychiatric disease, acute or chronic; Any suicidal actuations (Columbia suicide severity rating-scale, CSSR-S); Any history of drug hypersensitivity, asthma, urticaria, multiple or severe allergies or drug allergies as well as current hay fever; Any history of hypersensitivity to the IMPs or components thereof; Any history of chronic or recurrent metabolic, renal, hepatic, pulmonary, gastrointestinal, neurological (esp. history of epileptic seizures), endocrinological, immunological, psychiatric or cardiovascular disease, myopathies, and bleeding tendency; Infection or inflammation within 1 month prior to first dosing; Clinically significant laboratory values outside the reference range; Clinically significant increased value of glycosylated hemoglobin; Positive test for HIV antibodies or Hepatitis B-virus or Hepatitis C-virus; Positive Mendel–Mantoux test; Blood donation of 500 mL or more within 3 months prior to screening; Having received any blood transfusions or blood components within 2 months prior to screening; Participation in the treatment phase of a clinical trial within 3 months prior to screening or blocked by the follow-up period of a previous clinical trial before signing informed consent to this trial; Women of childbearing potential not using a highly effective method of birth control; Women who are pregnant or breast-feeding; Male subjects who are not surgically sterile have to use contraception during sexual intercourse with women of childbearing potential; Subject is in custody; Criteria which in the opinion of the investigator preclude participation; Previous assignment to treatment (e.g. randomization) during this study; Close affiliation with the investigator; Unable/unwilling to comply with study restrictions

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7595
Ander register	METC : METC NL67468.056.18

Resultaten