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

No registrations found.

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

Summary

ID

NL-OMON23997

Source
Nationaal Trial Register

Brief title
ENX-201-CR-001

Health condition

Multiple Sclerosis (relapses)

Sponsors and support

Primary sponsor: EnhanX Biopharm Inc.
Source(s) of monetary or material Support: EnhanX Biopharm Inc

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

1. Leeds Sleep Evaluation Questionnaire (LSEQ) scores in comparison to active comparator and placebo
2. Changes in adrenocorticotropic hormone (ACTH) in comparison to active comparator and placebo
3. Changes in lymphocyte count and lymphocyte differentiation
4. Complement (AP50, C3d, MBL), and inflammation parameters (C-reactive protein [CRP])
5. Treatment-emergent adverse events (TEAEs), infusion reactions, safety laboratory, vital signs, electrocardiogram (ECG), body weight, concomitant medication, physical examination

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-10-2018
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7595
Other	METC : METC NL67468.056.18

Study results