A Double-Blind, Placebo-Controlled, Single Ascending Dose Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of CCX507-H in Healthy Male and Female Subjects

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Primary:to evaluate the safety and tolerability of single oral doses of CCX507-H, over a range of 3 dose levels, in healthy male and female subjectsSecondary:to evaluate the following:* Single dose pharmacokinetic profile (PK) of CCX507-H over a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON36896

Source
ToetsingOnline

Brief title
CCX507-H SAD/FE study

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory bowel diseases

Research involving
Human

Sponsors and support

Primary sponsor: Chemocentryx
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: CCX507-H, Food effect, Inflammatory bowel diseases, Single dose

Outcome measures

Primary outcome

Pharmacodynamics: Effective amount of CCX507 and/or metabolites, PK/PD ratio

Pharmacokinetics: CCX507 concentrations (and possible metabolites),

plasma/urine concentration

Safety: adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination

Secondary outcome

NA

Study description

Background summary

CCX507-H is a new investigational compound that may eventually be used for the treatment of inflammatory bowel diseases, such as Chron*s disease. CCX507-H is not registered as a drug. This is the first time that this compound is being given to humans.

Study objective

Primary:
to evaluate the safety and tolerability of single oral doses of CCX507-H, over a range of 3 dose levels, in healthy male and female subjects

Secondary:
to evaluate the following:

* Single dose pharmacokinetic profile (PK) of CCX507-H over a range of 3 dose levels;
* The relative PK profile of CCX507-H given as different formulations;
* The effect of food on the PK profile of CCX507-H; and
* The relationship between CCX507 plasma concentrations and inhibition of C-C chemokine receptor 9 (CCR9)-mediated cell migration

Study design

Screening and follow-up:
clinical laboratory, full physical examination, ECG, vital signs; at eligibility screening: medical history, drug screen, HBsAg, anti HCV, anti-HIV 1/2 and pregnancy test (females only)

Observation period:
in clinic from -18h (Day -1) up to 24h (Day 2) after drug administration (Day 1) with ambulatory visits on Day 3 and 4
cohort 3b and 3c will return for a second (similar) period (food-effect) with a wash-out of 7 days between the two dosing days

Blood sampling:
For pharmacokinetics:
Prior to administration of study medication (Time 0), and at Hours 0.08 (5 minutes post dose), 0.25, 0.5, 1, 1.5, 2, 3, 4, 6, 9, 12, 16, 20, 24, 48, and 72 after administration of study medication.
For pharmacodynamics:
At baseline (within 2 hours prior to dosing), and at Hours 2, 12, and 24 after administration of study medication

Urine sampling:
For pharmacokinetics: Day 1 at interval 0-6h

Safety assessments:
Adverse events throughout the study; clinical laboratory, hematology, urinalysis, physical examination, vital signs, 12-lead-ECG and weight at screening and follow-up

Intervention

Cohort 1: 3 mg CCX507-H or placebo as dosing solution in the fasted state
Cohort 2: 10 mg CCX507-H or placebo as dosing solution in the fasted state
Cohort 3a: 30 mg CCX507-H or placebo as dosing solution in the fasted state
Cohort 3b:
Period 1: 30 mg CCX507-H or placebo in gelatin capsules in the fasted state
Period 2: 30 mg CCX507-H or placebo in gelatin capsules in the fed state
Cohort 3c:

Period 1: 30 mg CCX507-H or placebo as a semi-solid formulation in gelatin capsules in the fasted state
Period 2: 30 mg CCX507-H or placebo as a semi-solid formulation in gelatin capsules in the fed state

Study burden and risks

* Registration of adverse effects: During the entire investigation all adverse effect you report will be documented.
* Blood draw, indwelling canula: During this study not more than 600 ml of blood will be drawn. An indwelling cannula will be used once (per period, so in total twice for Group 3b and 3c). The remainder of the blood draws will be drawn by direct puncture of the vein.
* Collection of urine: Urine will be collected starting after dosing until 6 hours after administration of CCX507-H
* Heart trace (ECG*s): ECG*s will be made regularly: specifically on the day(s) of study drug administration

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy male and female
19-65 years inclusive
BMI 18.5 - 30.0 inclusive
non-smoker

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS.
Participation in another drug study within 60 days prior to randomization.
Any donation of blood(products) or significant blood loss within 56 dagen prior to screening.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2012
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-11-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EudraCT	EUCTR2012-004393-25-NL
CCMO	NL42605.056.12