A study to investigate the safety, tolerability and absorption and elimination of CCX507-B, a new drug for the treatment of patients with inflammatory bowel diseases, in healthy male and female subjects.

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

Summary

ID

NL-OMON40895

Source
ToetsingOnline

Brief title
CCX507-B SAD/MAD Study.

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease., Inflammatory bowel diseases

Research involving

Human

Sponsors and support

Primary sponsor: ChemoCentryx, Inc.
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: CCX507-B, inflammatory bowel diseases, Multiple dose, Single dose

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the safety and tolerability

of single and multiple oral doses of CCX507-B, over a range of 3 dose levels,

in healthy male and female subjects.

Secondary outcome

* The effect of food on the PK profile of CCX507-B; and

* The relationship between CCX507 plasma concentrations and blockade of the C-C

chemokine receptor 9 (CCR9) on circulating leukocytes.

Study description

Background summary

CCX507-B is a new investigational compound that may eventually be used for the treatment of inflammatory bowel diseases, such as Crohn*s disease. The active part of CCX507-B is CCX507. CCX507 is capable of blocking a protein that is involved in inflammatory reactions in the bowels. CCX507-B is in development and not registered as an approved drug, but has been given to humans before. In addition, CCX507 has also been administered to humans in the form of CCX507-H (this has a slightly different composition but the same active part).

Study objective

The purpose of the study is to investigate to what extent CCX507-B is safe and

tolerated. It will also be investigated how quickly and to what extent CCX507-B is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, the effect of the compound on the white blood cells (blood cells actively involved in the immune response) will be investigated (this is called pharmacodynamics). Finally, the effect of food on the effectiveness of the compound will be investigated.

Study design

The study will consist of 2 periods. In the first period the subject will receive once CCX507-B or placebo. In the second period the subjectl receive multiple doses of CCX507-B or placebo. If the subject participates in Group 1 or 2, they will receive CCX507-B or placebo first once daily for 4 days and thereafter twice daily for 3 days. If they participate in Group 3, they will receive CCX507-B or placebo once daily for 7 days. CCX507-B and placebo will be given in the form of oral capsules.

Intervention

Group 1a:
30 mg CCX507-B or placebo once (in fasted state)
30 mg CCX507-B or placebo once daily (in fasted state)
30 mg CCX507-B or placebo twice daily (in fasted state)

Group 1b:
30 mg CCX507-B or placebo once (after breakfast)
30 mg CCX507-B or placebo once daily (after breakfast)
30 mg CCX507-B or placebo twice daily (after breakfast and dinner)

Group 2a:
60 mg CCX507-B or placebo once (in fasted state)
60 mg CCX507-B or placebo once daily (in fasted state)
60 mg CCX507-B or placebo twice daily (in fasted state)

Group 2b:
60 mg CCX507-B or placebo once (after breakfast)
60 mg CCX507-B or placebo once daily (after breakfast)
60 mg CCX507-B or placebo twice daily (after breakfast and dinner)

Group 3a:
90 mg CCX507-B or placebo once (in fasted state)
90 mg CCX507-B or placebo once daily (in fasted state)

Group 3b:
90 mg CCX507-B or placebo once (after breakfast)
90 mg CCX507-B or placebo once daily (after breakfast)

Study burden and risks

Blood sampling, indwelling cannula: During this study less than 500 milliliters of blood will be drawn.
An indwelling cannula will be used once per period (so in total twice). The remainder of the blood draws will be drawn by direct puncture of the vein.
Collection of urine, feces and expired air.
Urine will be collected for 24 hours starting after administration of CCX507-B or placebo on Day 7 of Period 2.
Vital signs: Blood pressure, pulse rate and body temperature will be measured regularly in supine position.
On several occasions, this will also be done in the standing position.
Heart trace (ECG): ECGs will be made regularly: especially frequent on the days of first medication administration in each period (Days 1) and on the last day of medication administration in Period 2 (Day 7).

Contacts

Public
ChemoCentryx, Inc.

Maude Avenue 850
Mountain View CA 94043
US
Scientific
ChemoCentryx, Inc.

Maude Avenue 850
Mountain View CA 94043
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Healthy male or female
18 - 65 years inclusive
BMI 18.0 -30.0 kilograms/meter2
non smoker

Exclusion criteria

Suffering form 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 days prior to screening.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-03-2014
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	EUCTR2014-000373-39-NL
CCMO	NL48148.056.14