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Clinical trial to evaluate the safety and tolerability of CCX507-B in healthy subjects

Submission date 18/04/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/05/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/05/2014	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Drug CCX507-B is being studied as a possible treatment for patients with inflammatory bowel diseases (IBD) such as ulcerative colitis (UC) or Crohns disease (CD). Patients with these diseases suffer considerable lifestyle disruption and disability due to their condition. As the disease progresses, it often leads to patients needing repeated surgeries to remove affected areas of the stomach and intestine. Therefore, a critical need for safe and effective non-surgical treatment of UC still remains.

Who can participate?
This study will include 30 healthy men and women aged 18-65.

What does the study involve?
The subjects will be randomly allocated to take CCX507-B or a placebo (sugar pill), administered orally. First, they will consume this pill once and later, they will consume this pill for a week. Participants will be followed up for 3 weeks.

What are the possible benefits and risks of participating?
Since this study mainly looks at the safety and tolerability of CCX507-B, there is likely no benefit for study subjects, other than the knowledge that they are potentially helping us understand how to use the medication in future studies. Safety risk is considered to be low, because CCX507-B has been tested safely in nonclinical studies.

Where is the study run from?
Pharmaceutical Research Associates Group B.V., Netherlands.

When is the study starting and how long is it expected to run for?
This study started in April 2014 and runs until June 20154.

Who is funding the study?
ChemoCentryx, Inc. (USA).

Who is the main contact?
Ms Antonia Potarca
apotarca@chemocentryx.com

Contact information

Type(s)
Scientific

Contact name
Ms Antonia Potarca

Contact details
850 Maude Avenue
Mountain View
United States of America
94043
650-210-2900
apotarca@chemocentryx.com

Additional identifiers

Protocol serial number
CL002_507

Study information

Scientific Title
A double-blind, placebo-controlled, single and multiple ascending dose phase 1 study to evaluate the safety, tolerability, and pharmacokinetics of CCX507-B in healthy male and female subjects

Study objectives
CCX507-B will be safe and well tolerated at all dose levels tested.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Independent Ethics Committee of the Foundation Evaluation of Ethics in Biomedical Research, Assen, the Netherlands,10/03/2014

Primary study design
Interventional

Study design
Double-blind placebo-controlled study with two study periods. Period 1 will be a single dose period and Period 2 will be a multiple dose period.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inflammatory Bowel Diseases (IBD) such as ulcerative colitis (UC) or Crohns disease (CD)

Interventions
CCX507-B (30, 60 and 90 mg CCX507-B single dose and multiple doses for 7 days) or placebo. Period 1 involves subjects being randomized to CCX507-B or placebo and being dosed a single time. Period 2 involved subjects being randomized to CCX507-B or placebo and being dosed over a period of 7 days. After the conclusion of Period 2, subjects are followed for 3 weeks.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
CCX507-B

Primary outcome(s)
Safety and tolerability of CCX507-B. Safety is measured by adverse event, serum chemistry, urinalysis, and hematology assessments at Baseline, Days 2 and 4 after the single dose and Baseline, Days 2, 4, 8 and 15 of the multi-dose period.

Key secondary outcome(s)
Pharmacokinetic and pharmacodynamic profiles of CCX507-B. Pharmacokinetic profile is assessed on all study days, i.e., Days 1 through 4 of the single dose period and Days 1 through 15 of the multi-dose period. Pharmacodynamic markers are assessed at Baseline and on Days 1 and 2 of the single-dose period, and at Baseline and on Days 1, 2, 4, 5, 7, and 8 of the multi-dose period.

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Male or female subjects, aged 18-65 inclusive
2. Willing and able to give written Informed Consent and to comply with the requirements of the study protocol
3. Negative result of the human immunodeficiency virus (HIV) screen, the hepatitis B screen, and the hepatitis C screen
4. Female subjects of childbearing potential, and male subjects with partners of childbearing potential, may participate if adequate contraception is used

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Women who are pregnant or breastfeeding
2. History of use of tobacco and/or nicotine-containing products within the 3 months prior to study entry
3. History of drug abuse within 1 year prior to study entry
4. History of alcohol abuse within 5 years prior to study entry
5. History of any form of cancer
6. Consumed alcoholic beverages, or any food or drink containing grapefruit or Seville oranges within 48 hours prior to Day -1
7. History or presence of any medical condition or disease which, in the opinion of the Investigator, may place the subject at unacceptable risk for study participation
8. Donated or lost more than 50 mL of blood or blood products within 56 days prior to screening, or donated plasma within 7 days of randomization
8. Subject's hemoglobin less than the lower limit of normal at screening
9. Participated in any clinical study of an investigational product within 60 days prior to randomization
10. Subject has any evidence of hepatic disease; aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, or bilirubin > 1.5 x the upper limit of normal
11. Subject has any evidence of renal impairment; serum creatinine > 1.5 x upper limit of normal
12. Subject's urine tested positive at Screening and/or on Study Day -1 for any of the following: opioids, amphetamines, cannabinoids, benzodiazepines, barbiturates, cocaine, cotinine, or alcohol

Date of first enrolment
30/04/2014

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Netherlands

United States of America

Study participating centre
850 Maude Avenue
Mountain View
United States of America
94043

Sponsor information

Organisation
ChemoCentryx, Inc. (USA)

ROR
https://ror.org/04gp12571

Funder(s)

Funder type
Industry

Funder Name
ChemoCentryx, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration