

A multinational double-blind placebo-controlled, parallel group study to evaluate the efficacy and safety of CCX282_B in subjects with moderate to severe Crohns disease

Submission date 21/01/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/05/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/06/2014	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00306215

Protocol serial number

CL004_282

Study information

Scientific Title

Acronym

CCX282-B

Study objectives

To determine whether CCX282-B is effective in inducing and then maintaining treatment response (based on Clinical Disease Activity Index [CDAI] changes from baseline) in patients with Crohns disease.

Please note that this trial was preceded by another trial registered on the ISRCTN - see <http://www.controlled-trials.com/ISRCTN58248439>.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval has been received in all countries in which this trial is ongoing. Lead centre ethics approval received from West Glasgow Ethics Committee 1 on 02/05/2006, ref: 06/S0703/42

Primary study design

Interventional

Study design

Multinational double-blind placebo-controlled parallel-group study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Moderate to severe Crohn's disease

Interventions

An investigational medication, CCX282-B administered orally via capsule versus placebo for 12 weeks:

1. CCX282-B 250 mg four times a day (qd)
2. CCX282-B 500 mg qd
3. CCX282-B 250 mg twice a day (b.i.d)
4. Placebo

Four-week active phase CCX282-B 250 mg, b.i.d. and 36-week maintenance phase 250 mg CCX282-B b.i.d. or placebo, four-week safety monitoring.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

CCX282-B

Primary outcome(s)

1. CDAI 70-point response at day 57
2. Relapse rate during the maintenance period
3. Safety and tolerability of CCX282-B

Key secondary outcome(s)

1. CDAI 100-point response and CDAI remission rate
2. Change in C-reactive protein from baseline

Completion date

31/03/2009

Eligibility

Key inclusion criteria

1. Male or female subjects, at least 18 years old
2. Active, moderate to severe Crohns disease
3. CDAI between 250 and 450
4. Fasting serum C-reactive proterin (CRP) concentration above 7.5 mg/L
5. If on therapy for Crohns disease, must have been on a stable treatment regimen for at least four weeks
6. If a female of childbearing potential, or if a male whose partner is a woman of childbearing potential, the subject must agree to use adequate contraception during the study
7. The subject must be willing and able to give written informed consent and comply with the requirements of the study protocol
8. No more than 100 cm small bowel resection
9. If taking oral antibiotics chronically, must have continuous use for at least four weeks prior to randomisation and at stable doses for at least two weeks prior to randomisation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. If female, the subject is pregnant or breastfeeding
2. Use of cyclosporin, tacrolimus, sirolimus, or mycophenolate mofetil and/or greater than 20 mg prednisone or a prednisone-equivalent, parenteral glucocorticoids or corticotrophin, or any experimental treatment for Crohn's disease within four weeks prior to study entry
3. Tumour necrotising factor (TNF) inhibitor or natalizumab use during 12 weeks prior to study entry
4. History or presence of any medical or psychiatric condition or disease, or laboratory abnormality that may place the subject at unacceptable risk for study participation and completion
5. Bowel surgery within 12 weeks prior to randomisation and/or planned or likely to require bowel surgery during the study
6. Presence of symptomatic obstructive stricture
7. Active tuberculosis, hepatitis B, C and/or human immunodeficiency virus (HIV) infection
8. History of any form of cancer within five years prior to study entry except for localised tumours that have been resected successfully
9. History of infection requiring intravenous antibiotics, a serious infection within 12 weeks of randomisation
10. Ulcerative or indeterminate colitis

Date of first enrolment

13/03/2006

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

United Kingdom

England

Australia

Austria

Belgium

Brazil

Bulgaria

Canada

Czech Republic

Denmark

France

Germany

Hungary

Israel

Netherlands

Poland

South Africa

Sweden

Study participating centre
Dept of Gastroenterology, Level 5
Oxford
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OX3 9DU

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013		Yes	No