ISRCTN61635363 https://doi.org/10.1186/ISRCTN61635363

# 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

**Registration date**
30/05/2008

**Overall study status**
Completed

**Last Edited**
16/06/2014

**Condition category**
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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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

## Study design
Multinational double-blind placebo-controlled parallel-group study

## Primary study design
Interventional

## 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**
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# 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 |