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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/05/2008	**Overall study status** Completed	
Last Edited 16/06/2014	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00306215

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

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

Overall study start date
13/03/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
423

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
Australia

Austria

Belgium

Brazil

Bulgaria

Canada

Czech Republic

Denmark

England

France

Germany

Hungary

Israel

Netherlands

Poland

South Africa

Sweden

United Kingdom

Study participating centre
Dept of Gastroenterology, Level 5
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Sponsor information

Organisation
ChemoCentryx, Inc. (USA)

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Sponsor type
Industry

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http://www.chemocentryx.com

ROR
https://ror.org/04gp12571

Funder(s)

Funder type
Industry

Funder Name
ChemoCentryx, Inc. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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