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Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn's Disease

Submission date 13/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 21/12/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/01/2021	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

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)
NCT00102921

Protocol serial number
CL003_282_b

Study information

Scientific Title
Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn’s Disease

Acronym
CCX

Study objectives
The purpose of this research study is to investigate the effects of an investigational medication, called CCX282-B, on safety and on some of the symptoms of Crohn’s Disease in patients who are experiencing an active flare-up of moderate to severe Crohn’s Disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Crohn's Disease

Interventions
An investigational medication, called CCX282-B (capsules), compared to placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
CCX282-B

Primary outcome(s)
The primary immunologic and clinical activity objective of this study is to provide pilot information regarding the immunologic and clinical activity of daily oral doses of CCX282-B in the treatment of moderate to severe Crohn’s Disease, based on changes in the Crohn’s Disease Activity Index (CDAI).

Key secondary outcome(s))
Secondary immunologic and clinical activity objectives include evaluation of the effect of CCX282-B on the Inflammatory Bowel Disease Questionnaire (IBDQ) instrument, C-reactive protein (CRP), the endoscopic appearance and biopsy of the colon and terminal ileum, and markers of leukocyte subsets and activation status.

Completion date
01/02/2006

Eligibility

Key inclusion criteria
1. Diagnosis of moderate to severe Crohn's Disease in small intestine; disease must be active at the time of study entry
2. Use of adequate and approved methods of birth control throughout the study period
3.
Willing and able to sign an informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding
2. Infection with hepatitis B, hepatitis C, or human immunodeficiency virus (HIV; the virus that causes AIDS)
3. Abuse of alcohol or of illegal drugs

Date of first enrolment
01/08/2004

Date of final enrolment
01/02/2006

Locations

Countries of recruitment
Netherlands

Study participating centre

Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
ChemoCentryx (USA)

ROR
https://ror.org/04gp12571

Funder(s)

Funder type
Industry

Funder Name
ChemoCentryx

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration