# The safety and efficacy of CCX354-C in subjects with rheumatoid arthritis

Submission date	Recruitment status	Prospectively registered
11/12/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
19/02/2010	Completed	Results
Last Edited	Condition category	Individual participant data
25/10/2022	Musculoskeletal Diseases	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT01027728

Protocol serial number

CL003\_354

# Study information

#### Scientific Title

A randomised, double-blind, placebo-controlled, phase I/II study to evaluate the safety and efficacy of CCX354-C in subjects with rheumatoid arthritis

#### Acronym

CARAT-1

#### **Study objectives**

CCX354-C is safe and well tolerated in subjects with stable rheumatoid arthritis (RA) based on subject incidence of adverse events.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

1. Belgium: Comite d'ethique Hospitalo-Facultaire Universitaire de Liege approved on 30/10/2009, ref: 2009/200

#### Added 15/03/2010:

2. Romania: National Ethic Commission for the Clinical Studies of Medicine approved on 03/12/2009, ref: 3243,3863

#### Study design

Randomised double-blind placebo-controlled phase I/II study

#### Primary study design

Interventional

## Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Rheumatoid arthritis

#### Interventions

- 1. 100 mg CCX354-C or placebo once daily for 14 days
- 2. 100 mg CCX354-C or placebo twice daily for 14 days
- 3. 200 mg CCX354-C or placebo once daily for 14 days

Total duration of treatment: 14 days Total duration of follow-up: 14 days

#### Intervention Type

Drug

#### Phase

Phase I/II

## Drug/device/biological/vaccine name(s)

CCX354-C

#### Primary outcome(s)

Subject incidence of adverse events over 14 days of dosing

#### Key secondary outcome(s))

Evaluate possible interaction with methotrexate at a number of dose levels in subjects with stable RA; pharmacokinetic (PK) measurements on Day 14 and 15

#### Completion date

30/03/2010

# Eligibility

#### Key inclusion criteria

- 1. Male or female subjects, aged 18 75 years inclusive, with stable RA based on American College of Rheumatology (ACR) criteria for at least 3 months (subjects do not need to have active RA for Stage A of the study)
- 2. Subjects must have been on a stable dose of methotrexate (7.5 to 25 mg/week) taken orally, subcutaneously, or intramuscularly, but not intravenously, for greater than or equal to 8 weeks prior to randomisation
- 3. If a subject is also taking sulfasalazine or hydroxychloroquine, the subject must have been on a stable dose of these medications for at least 8 weeks prior to randomisation
- 4. If a subject is on corticosteroid therapy, the dose must not exceed 10 mg prednisone or equivalent and the subject must have been on a stable dose for at least 4 weeks prior to randomisation
- 5. Willing and able to give written Informed Consent and to comply with the requirements of the study protocol
- 6. Negative result of the human immunodeficiency virus (HIV) screen, the hepatitis B screen, and the hepatitis C screen
- 7. Judged to be otherwise healthy by the Investigator, based on medical history, physical examination (including electrocardiogram [ECG]), and clinical laboratory assessments 8. Female subjects of childbearing potential, and male subjects with partners of childbearing potential, may participate if adequate contraception is used during, and for at least the four weeks after, any administration of study medication. Adequate contraception is defined as usage by at least one of the partners of a barrier method of contraception, together with usage by the female partner, commencing at least three months prior to screening, of a stable regimen of any form of hormonal contraception or an intra-uterine device. Use of abstinence alone is not considered adequate. Use of a barrier method alone is considered adequate only if the male partner was vasectomized at least six months prior to Screening. Use of a double-barrier method of contraception is acceptable.

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Diagnosed with RA prior to 16 years of age
- 2. Women who are pregnant, breastfeeding, or have a positive serum pregnancy test at Screening
- 3. History within one year prior to randomisation of illicit drug use
- 4. History of alcohol abuse at any time in the past
- 5. Use of infliximab, adalimumab, abatacept, certolizumab, golimumab, or tocilizumab within 8 weeks of randomisation
- 6. Use of leflunomide within 6 months of randomisation
- 7. Use of etanercept or anakinra within 4 weeks of randomisation
- 8. Use of rituximab or ocrelizumab, or cytotoxic agents, such as cyclophosphamide or chlorambucil, within one year of randomisation
- 9. Currently taking cytochrome P450 inhibitors including protease inhibitors such as ritonavir, indinavir, nelfinavir, or macrolide antibiotics such as erythromycin, telithromycin, clarithromycin, or azole antifungals such as fluconazole, ketoconazole, itraconazole, or cimetidine, nefazodone, bergamottin (constituent of grapefruit juice), quercetin, aprepitant, or verapamil
- 10. History or presence of any form of cancer within the 10 years prior to randomisation, with the exception of excised basal cell or squamous cell carcinoma of the skin, or cervical carcinoma in situ or breast carcinoma in situ that has been excised or resected completely and is without evidence of local recurrence or metastasis
- 11. Evidence of tuberculosis based on chest X rays, tuberculin skin test, QuantiFERON®-TB Gold test, or T-SPOT®.TB test performed during screening
- 12. Presence of Felty's syndrome, psoriatic arthritis, or other auto-immune diseases
- 13. Major surgery (including joint surgery) within 12 weeks prior to randomisation
- 14. Subject's haemoglobin is less than 11 g/dL (6.83 mmol/L) at screening
- 15. Subject has any evidence of hepatic disease; aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, or bilirubin greater than 1.5  $\times$  the upper limit of normal
- 16. Subject has any evidence of renal impairment; serum creatinine greater than 1.5 x upper limit of normal
- 17. The subject had an infection requiring antibiotic treatment within 4 weeks of randomisation
- 18. History or presence of any medical or psychiatric condition or disease, or laboratory abnormality that, in the opinion of the Investigator, may place the subject at unacceptable risk for study participation and may prevent the subject from completing the study
- 19. Participated in any clinical study of an investigational product within 30 days prior to randomisation

Date of first enrolment

08/12/2009

Date of final enrolment

30/03/2010

# Locations

#### Countries of recruitment

Belgium

Romania

94043

United States of America

Study participating centre ChemoCentryx, Inc. California United States of America

# 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

Not provided at time of registration

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type

Details

Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No

Yes