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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	[ ] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT01027728

Secondary identifying numbers
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

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 to request a patient information sheet

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 measure
Subject incidence of adverse events over 14 days of dosing

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

Overall study start date
08/12/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

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 x 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

United States of America

Study participating centre
ChemoCentryx, Inc.
California
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94043

Sponsor information

Organisation
ChemoCentryx, Inc. (USA)

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Sponsor type
Industry

Website
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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration