ISRCTN67054656 https://doi.org/10.1186/ISRCTN67054656

Evaluating the safety and efficacy of CCX354-C in subjects with rheumatoid arthritis partially responsive to methotrexate therapy

Submission date
30/11/2010

Recruitment status
No longer recruiting

Registration date
05/04/2011

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Musculoskeletal Diseases

[ ] 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

Contact name
Prof Paul-Peter Tak

Contact details
Division of Clinical Immunology and Rheumatology
Academic Medical Center
Meibergreef 9
Amsterdam
Netherlands
1105 AZ

Additional identifiers

ClinicalTrials.gov (NCT)
NCT01242917

Clinical Trials Information System (CTIS)
2010-019964-36

Protocol serial number
CL004_354

Study information

Scientific Title
A randomised, double-blind, placebo-controlled, phase II study to evaluate the safety and efficacy of CCX354-C in subjects with rheumatoid arthritis partially responsive to methotrexate therapy

Acronym
CARAT-2

Study objectives
That CCX354-C will be safe and well tolerabate by subjects with rheumatoid arthritis (RA) who had an inadequate response to methotrexate treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the University Hospital and Medical School, Leige (Comite d'Ethique Hospitalo-Facultaire Universitaire de Leige [707]) approved on the 26th August 2010 (ref: 2010 /112)

Study design
Multicentre double blind randomised placebo controlled parallel group study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
150 subjects with RA, partially responsive to methotrexate therapy will be randomised to one of the following treatment arms:
1. Placebo comparator: placebo tablet twice daily for 12 weeks + methotrexate
2. CCX354-C twice daily: 100 mg tablet twice daily for 12 weeks + methotrexate
3. CCX354-C once daily: 100 mg (2) tablets once daily for 12 weeks + methotrexate

To ensure patient safety, all patients will be followed for 28 days from the end of the intervention.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
CCX354-C, methotrexate

Primary outcome(s)
Subject incidence of adverse events at 12 weeks

Key secondary outcome(s))
1. Disease Activity Score 28 using C-reactive protein (DAS28-CRP)
2. American College of Rheumatology (ACR) response criteria

All outcomes will be assessed at the end of the intervention period (12 weeks).

Completion date
30/08/2011

Eligibility

Key inclusion criteria
1. Adult subjects, with active RA, with at least 8 swollen joints, and 8 tender joints
2. Serum C-reactive protein (CRP) above upper limit of normal
3. Must have been on stable dose methotrexate for less than or equal to 8 weeks prior to randomisation
4. Willing and able to give written Informed Consent and to comply with the requirements of the study protocol
5. 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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Diagnosed with RA prior to 16 years of age
2. Have received sulfasalazine, azathioprine, 6-mercaptopurine, mycophenolate mofetil, tetracycline, cyclosporine, gold, tacrolimus, sirolimus, or other disease modifying anti-rheumatic drug (DMARD) within 8 weeks of randomisation
3. Use of infliximab, adalimumab, abatacept, certolizumab, golimumab, or tocilizumab within 8 weeks of randomisation
4. Use of leflunomide within 6 months of randomisation

5. Use of etanercept or anakinra within 4 weeks of randomisation
6. Use of a B-cell depleting agent such as rituximab or ocrelizumab, or cytotoxic agents, such as cyclophosphamide or chlorambucil, within one year of randomisation

Date of first enrolment
14/09/2010

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
Belgium

Czech Republic

Germany

Hungary

Netherlands

Poland

Romania

Ukraine

Study participating centre
Division of Clinical Immunology and Rheumatology
Amsterdam
Netherlands
1105 AZ

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?
Results article	results	01/03/2013		Yes	No
Abstract results	conference abstract	08/11/2011		No	No
Abstract results	conference abstract	01/06/2013		No	No