Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Multicenter, Open-Label, Phase IV Study to Evaluate the Safety,Tolerability, and Efficacy of Tocilizumab in Patients with Active Rheumatoid arthritis on background non-biologic DMARDs who have an inadequate response to current non-biologic DMARD and/or Anti- TNF therapy

Protocol summary

Summary

This open-label single-arm study will evaluate the safety, tolerability and efficacy of tocilizumab [RoActemra/Actemra] in patients with moderate to severe rheumatoid arthritis who experience an inadequate clinical response to a stable dose of non-biologic disease modifying anti-rheumatic drugs (DMARD) or anti-tumor necrosis factors (TNFs). RoActemra/Actemra will be administered as a monotherapy or in combination with DMARDs. RoActemra/Actemra will be administered as intravenous infusion at a dose of 8 mg/kg every 4 weeks for a total of 6 infusions. The anticipated time on study treatment is 24 weeks. The target sample size is 50-150 patients. Primary outcomes will be safety and tolerability: AEs, laboratory parameters [Time Frame: AEs: event-driven assessments throughout study, laboratory assessments every 4 weeks for 24 weeks]. Secondary outcomes will be number and percentage of patients achieving an improvement in DAS28 score (reduction of 1.2 units), low disease activity (DAS28)

General information

Acronym

STEARA

IRCT registration information

IRCT registration number: **IRCT201008312641N3**
Registration date: **2010-10-21, 1389/07/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-10-21, 1389/07/29

Registrant information

Name

Fereydoun Davatchi

Name of organization / entity

Rheumatology Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Akbarieh Pharma Company

Expected recruitment start date

2010-09-30, 1389/07/08

Expected recruitment end date

2010-11-30, 1389/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Multicenter, Open-Label, Phase IV Study to Evaluate the Safety,Tolerability, and Efficacy of Tocilizumab in Patients with Active Rheumatoid arthritis on background non-biologic DMARDs who have an inadequate response to current non-biologic DMARD and/or Anti- TNF therapy

Public title
Multicenter, Open-Label, Phase IV Study to Evaluate the Safety,Tolerability, and Efficacy of Tocilizumab in Patients with Active Rheumatoid arthritis on background non-biologic DMARDs who have an inadequate response to current non-biologic DMARD and/or Anti- TNF therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: age more than 18 years, moderate to severe rheumatoid arthritis (DAS28 >3.2) of 6 months duration, inadequate clinical response to non-biologic DMARDs or anti-TNF, body weight less than150 kg
Exclusion Criteria: rheumatic autoimmune disease or inflammatory joint disease other than RA, major surgery within 8 weeks prior to screening or planned major surgery within 6 months following screening
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov
Secondary trial Id
NCT01089023
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Central Ethic committee in medical research
Street address
Infront of Avesta Park, Azadi Street
City
Tehran
Postal code
Approval date
2010-06-08, 1389/03/18
Ethics committee reference number
206/پ89ص

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis
ICD-10 code
M05
ICD-10 code description
Seropositive Rheumatoid Arthritis

Primary outcomes

1

Description
Liver transaminase level
Timepoint
Each visit
Method of measurement
Liver Alkaline Phosphatase ,ALT ,AST

2

Description
Lipid Level
Timepoint
Each visit
Method of measurement
Lipid Profile

3

Description
Neutrophil count
Timepoint
Each visit
Method of measurement
CBC/dif

4

Description
To assess the safety
Timepoint
Each visit
Method of measurement
AEs happend within 24 weeks of treatment

5

Description
Infusion Reaction
Timepoint
Each visit
Method of measurement

An Infusion Reaction is defined as an AE occurring within 24 hours following the infusion

6

Description
Major adverse cardiac event
Timepoint
Each visit
Method of measurement
Physical Examination,BP,EKG

7

Description
Strokes
Timepoint
Each Visit
Method of measurement
Physical Examination ,BP,EKG

Secondary outcomes

1

Description
Severity of Disease
Timepoint
Each visit
Method of measurement
DAS Score

Intervention groups

1

Description
an infusion of 8 mg/kg IV TCZ every 4 weeks total of 6 infusions, for 24 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology research center
Full name of responsible person
Dr Bahar Sadeghi
Street address
North karegar St
City
Tehran

2

Recruitment center
Name of recruitment center
Loghman Rheumatology Centre
Full name of responsible person
Dr Arman Ahmadzadeh
Street address
Ghazvin Sq. Kargar St
City
Tehran

3

Recruitment center
Name of recruitment center
Alzahra Rheumatology Centre
Full name of responsible person
Dr Hadi Karimzadeh
Street address
Hakim Nezami St
City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Akbarieh Company
Full name of responsible person
Dr Shahoo Shekarchi
Street address
no 100 west bozorgehr Vesal Shirazi St
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Akbarieh Company
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Rheumatology Research Center
Full name of responsible person
Dr Bahar Sadeghi
Position
General Practitioner / Head of Rheumatology Centre
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty