Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A Phase III, randomized, two-armed, double-blind (patient and assessor blinded), parallel active controlled non-Inferiority clinical trial to determine the non-inferior therapeutic efficacy and safety of two disease-modifying anti rheumatic drugs (CinnoRA) versus Humira® for treatment of Active rheumatoid arthritis

Protocol summary

Summary

The purpose of this study is to compare the efficacy of adalimumab produced by CinnaGen company and AbbVie adalimumab in subjects with active Rheumatoid Arthritis. Patients with diagnosis of active Rheumatoid arthritis according to EULAR criteria (European League Against Rheumatism) aged between 18 to 75 years will be included. Those with certain medical conditions like history of Multiple Sclerosis or Hepatitis C, Hepatitis B, HIV along with concomitant use of corticosteroids more than 10 mg/day prednisolone, will be excluded This is a randomized, double blind clinical trial in which adalimumab is administered subcutaneously 40 mg every other week in addition to current anti-rheumatic therapies for 136 eligible patients over six months. Changes from baseline in disease activity according to EULAR criteria and ACR (ACR20, ACR50, ACR70 will be assessed at 12 weeks and 24 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030321315N1**
Registration date: **2015-04-05, 1394/01/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-04-05, 1394/01/16

Registrant information

Name

Nassim Anjidani

Name of organization / entity

Orchid Pharmed

Country

Iran (Islamic Republic of)

Phone

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Email address

amini@orchidpharmed.com

Recruitment status

Recruitment complete

Funding source

CinnaGen Company

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Phase III, randomized, two-armed, double-blind (patient and assessor blinded), parallel active controlled non-Inferiority clinical trial to determine the non-inferior therapeutic efficacy and safety of two disease-modifying anti rheumatic drugs (CinnoRA) versus Humira® for treatment of Active rheumatoid arthritis

Public title

The effect of Adalimumab on treatment of Rheumatoid Arthritis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Are male or female aged 18-75 years at the time of signing the informed consent form; Have been diagnosed as having active Rheumatoid Arthritis according to the EULAR criteria; moderately to severely active RA for at least 6 months; Patients who have inadequate response to the treatment with usual non-biological regimen for at least 12 weeks according to their investigator judgment; Ability to comprehend and willingness to sign the Informed Consent Form for this study Exclusion criteria: liver Enzymes ALT or AST more than 2 Upper Limit Normal; Hemoglobin less than 8.5 mg/dL; Platelet count less than 125000 cell/mm3; WBC less than 3500 cell/mm3; Serum creatinine more than 2 mg/dL; Concomitant use of corticosteroids, prednisolone more than 10 mg/day or concomitant use of NSAIDS more than recommended dose of company; Treatment with intravenous, intramuscular, intra-articular and parenteral corticosteroids within 4 weeks prior to Day 1 more than 7.5 mg/daily ; Pregnancy, breasfeeding, or planning for being pregnant; History of CHF (Class III/IV) according to NYHA classification; demyelinating disorders, CHF; acute myocardial infarction or unstable angina within the previous 12 months prior to Screening, any malignancy within the previous 5 years prior to Screening, Any other disease or disorder which put the subject at risk if they are enrolled,, in the opinion of the Investigator, History of HIV, a positive serological test for HBV or HCV; Have a known hypersensitivity to human immunoglobulin proteins or other components of Humira or Adalimumab; Have been treated previously with any biological agents including any tumor necrosis factor inhibitor; Physical incapacitation (ACR functional Class IV or wheelchair-/bed-bound); Have had a serious infection or have been treated with intravenous antibiotics for an infection within 8 weeks or oral antibiotics within 2 weeks prior to screening; history of chronic or recurrent infection
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **136**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences
Street address
Sixth floor, Research Deputy of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulvard
City
Tehran
Postal code
Approval date
2014-12-06, 1393/09/15
Ethics committee reference number
26826

2

Ethics committee
Name of ethics committee
Research Ethics Committee of Kerman University of Medical Sciences
Street address
Ebn-e-Sina Ave, Jahad Blvd, Tehmaseb Abad Cross, Kerman., Iran
City
Kerman
Postal code
Approval date
2015-07-13, 1394/04/22
Ethics committee reference number
IR.KMU.REC.1394.126

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis
ICD-10 code
M05.8, M06
ICD-10 code description
Other seropositive rheumatoid arthritis ,Seronegative rheumatoid arthritis

Primary outcomes

1

Description
Assessment of efficacy Parameters of Adalimumab by AbbVie and Adalimumab by CinnaGen according to EULAR criteria
Timepoint
baseline, 3months and 6 months after intervention

Method of measurement
EULAR Criteria (The European League Against Rheumatism)

Secondary outcomes

1

Description
percentage of participants meeting ACR20 response criteria
Timepoint
baseline, 3months and 6 months after intervention
Method of measurement
ACR criteria (American College of Rheumatology)

2

Description
percentage of participants meeting ACR50 response criteria
Timepoint
baseline, 3months and 6 months after intervention
Method of measurement
ACR criteria (American College of Rheumatology)

3

Description
percentage of participants meeting ACR70 response criteria
Timepoint
baseline, 3months and 6 months after intervention
Method of measurement
ACR criteria (American College of Rheumatology)

4

Description
Safety and frequency of AEs
Timepoint
every 2 weeks until 6 months
Method of measurement
in-house Questionnaire according to literature

5

Description
Concentration of the anti-drug antibodies
Timepoint
Prior to treatment and at months 3 and 6
Method of measurement
Validated Enzyme-Linked Immunosorbent Assay (ELISA).

Intervention groups

1

Description
CinnaGen adalimumab (1 prefilled syringe of 40 mg/0.8 mL) as Subcutaneous injection, every other week for 6 months
Category
Treatment - Drugs

2

Description
AbbVie adalimumab (1 prefilled syringe of 40 mg/0.8 mL) as Subcutaneous injection, every other week for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatism Research Center, Doctor Shariati hospital
Full name of responsible person
Ahmadreza Jamshidi
Street address
Rheumatism Research Center, Doctor Shariati Hospital, North Kargar Avenue
City
Tehran

2

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Dr. Hadi Karim Zadeh
Street address
Al-Zahra Hospital, Soffeh Blvd, Shahis Keshvari, Esfahan.
City
Esfahan

3

Recruitment center
Name of recruitment center
Imam Ali Clinic
Full name of responsible person
Dr. Mohammad Mousavi
Street address
Imam Ali Clinic, Dr. Shariati, St., Shahr e Kord
City
Shahr e Kord

4

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Susan Ghasem Zadeh Soroush
Street address
Imam Reza Hospital, Etemad zadeh ave., West Fatemi, Tehran

City

5

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Dr. Arman Ahmad zadeh
Street address
Loghman Hospital, Makhsoos St., Lashgar Cross, South Kargar
City
Tehran

6

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
Dr. Mohammad Ali Nazari nia
Street address
Hafez Hospital, chamran Blvd, Shiraz
City

7

Recruitment center
Name of recruitment center
Beasat Clinic
Full name of responsible person
Dr. Mohammad Reza Shakibi
Street address
Beasat Clinic, 78th Alley, Shahid Rejaei, Kerman.
City
Kerman

8

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Zahra Rezaei Yazdi
Street address
Ghaem Hospital, Dr. Shariati St., Ahmad Abad, St., Ghaem Hospital
City
Mashhad

9

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr. Asghar Haji Abasi
Street address
Razi Hospital, Sardar Jangal Ave., Rasht
City
Rasht

10

Recruitment center
Name of recruitment center
Noor Complex
Full name of responsible person
Dr. Ali Asghar Ebrahimi
Street address
4th Floor, Noor Complex, Daneshgah Sq., Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
CinnaGen Company
Full name of responsible person
Somayeh Amini
Street address
No 10, Ninth street, Iranzamin Blvd, Shahrak-e-Gharb
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
CinnaGen 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
Orchid Pharmed Company
Full name of responsible person
Somayeh Amini
Position
Pharmacist (PharmD), Medical Manager
Other areas of specialty/work
Street address
No 10, Ninth street, Iranzamin Blvd, Shahrak-e-Gharb
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1465884171
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Ahmadreza Jamshidi
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MD, PhD of Rheumatology
Other areas of specialty/work
Street address
Rheumatism Research Center, Doctor Shariati Hospital, North Kargar Avenue
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1411713137
Phone
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Fax
Email
jamshida@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Orchid Pharmed Company
Full name of responsible person
Somayeh Amini
Position
Pharmacist (PharmD), Medical Manager
Other areas of specialty/work
Street address
No 10, Ninth street, Iranzamin Blvd, Shahrak-e-Gharb
City
Tehran
Postal code
1465884171
Phone
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Fax
+98 21 8856 1787
Email
amini.s@orchidpharmed.com
Web page address

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