

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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

+98 21 4347 3000

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, breastfeeding, 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 Boulevard

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, Jihad 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

City
Tehran

Postal code
1465884171

Phone
+98 21 8807 5724

Fax
+98 21 8856 1787
Email
amini.s@orchidpharmed.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rheumatism Research Center, Doctor Shariati Hospital
Full name of responsible person
Ahmadreza Jamshidi
Position
MD, PhD of Rheumatology
Other areas of specialty/work
Street address
Rheumatism Research Center, Doctor Shariati Hospital, North Kargar Avenue
City
Tehran
Postal code
1411713137
Phone
+98 21 8822 0065
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
+98 21 8807 5724
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