

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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/mm<sup>3</sup>; WBC less than 3500 cell/mm<sup>3</sup>; 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, 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

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**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**

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**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

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**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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+98 21 8807 5724

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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**  
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**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**  
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**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*