Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Efficacy of Adalimumab (MabAsia) versus Humira@ on activity score of Rheumatoid Arthritis: A Randomized Clinical Trial in refractory patients

Protocol summary

Summary

This study compare the efficacy of Adalimumab by Asia Padtan and Humira in the treatment of rheumatoid arthritis. Disease activity is measured based on the disease activity score (DAS) of American College of Rheumatology. Twenty percent reduction in DAS will be considered as response to treatment . This study also determine and compare the drugs side effects and adverse events in both groups. One hundred and five patients with active rheumatoid arthritis will be enrolled to the study from rheumatology clinic of Shariati Hospital for six months. Patients are allocated to both groups based on balanced random block method. Main inclusion criteria are: age 18 years old or more, active rheumatoid arthritis and no history of treatment with Humira. Main exclusion criteria are impaired liver function tests and pancytopenia. Patients, clinicians and monitoring committee are all blind. All patients receive combination therapy of methotrexate and subcutaneous injection of adalimumab for a period of 16 weeks. The primary outcome variable is disease activity score (DAS) of rheumatoid arthritis. The side effects and adverse events caused by the intervention will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090319025N1**
Registration date: **2015-09-24, 1394/07/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-24, 1394/07/02

Registrant information

Name

Mahdi Roohi

Name of organization / entity

MabAsia Biopharm

Country

Iran (Islamic Republic of)

Phone

+98 21885459612

Email address

h-faghihi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

MabAsia Company

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-05-23, 1396/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Adalimumab (MabAsia) versus Humira@ on activity score of Rheumatoid Arthritis: A Randomized Clinical Trial in refractory patients

Public title

Efficacy of MabAsia (Adalimumab) in Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:1-Age more 18 years old, 2- active Rheumatoid Arthritis, 3-not received Humira ® yet. exclusion criteria: 1-aminotransferase levels greater than twice the upper limit of normal and serum creatinine

level more than 2mg/dL, a hemoglobin level of 8.5 mg/dL or less, platelet count less than 125000 cells/mm3, leukocyte count less than 3500 cells/mm3 3- Concomitant therapy with doses of oral corticosteroids greater than 10 mg of prednisone per day ,and NSAIDs with doses greater than the maximum dose recommended by the manufacturer

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences, Ethics Committee

Street address
Keshavarz, Blvd., Ghos St., Central Organization, 6th fl.

City
Tehran

Postal code

Approval date
2015-01-21, 1393/11/01

Ethics committee reference number
92-04-41-27276-13694

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
Response to treatment for Rheumatoid Arthritis

Timepoint
Before beginning of treatment, after 3 months of treatment beginning, after 6 months of treatment beginning

Method of measurement
DAS 28 shows 20% improvement

Secondary outcomes

1

Description
side effects

Timepoint
Before intervention, After 3 months and after six months of therapy

Method of measurement
Clinically, by the rheumatologist, Cell Blood Count, Serum Biochemistry, Liver function test and Kidney function tests.

Intervention groups

1

Description
Drugs in intervention group: 1-Humira 40 mg every other week subcutaneously (2 pre-filled syringes 40 mg/0.8ml) 2-oral Methotrexate (MTX) 15 mg/week 3-Tablet prednisolone 10 mg/d 4-Tablet Ca+VitD 1000 mg,400 IU/d. Treatment period=6 months

Category
Treatment - Drugs

2

Description
Drugs in control group: 1-Adalimumab (MabAsia) 40 mg every other week ,subcutaneously (2 pre-filled syringes 40 mg/0.8ml) 2-oral methotrexate (MTX) 15 mg/week 3-Tablet prednisolone 10 mg/d 4-Tablet Ca+VitD 1000 mg,400IU/d. Treatment period=6 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rheumatology Research Center

Full name of responsible person

Ahmadreza Jamshidi

Street address

Rheumatology Research Center,Shariati Hospital,Kargar Av Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Younesian

Street address

Tehran, Kargar Avenue, Shariati Hospital

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research, Tehran University of Medical Sciences

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

MabAsia Biopharm

Full name of responsible person

Mehdi Roohi

Position

Dr. of Pharmacy

Other areas of specialty/work

Street address

Apt. 3, No. 48, Naghdi St., North Mofateh Ave.

City

Tehran

Postal code

Phone

+98 21885459612

Fax

+98 21 8854 5963

Email

maroohi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Reumatology Research Center

Full name of responsible person

Dr.Ahmadreza Jamshidi

Position

Head Rheumatology Research Center, Professor of Rheumatology

Other areas of specialty/work

Street address

Rheumatology Research Center,Shariati Hospital,Kargar Ave.,Tehran

City

Tehran

Postal code

Phone

+98 21 8822 0065

Fax

+98 21 8802 6956

Email

jamshida@sina.tums.ac.ir

Web page address

http://rrc.tums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Rheumatology Research Center, Tehran University of Medical Sciences

Full name of responsible person

Bahar Sadeghi

Position

Researcher

Other areas of specialty/work

Street address

Rheumatology Research Center, Shariati Hospital, Kargar Ave.

City

Tehran

Postal code

Phone

+98 21 8822 0065

Fax

+98 21 8802 6956

Email

b-sadeghia@farabi.tums.ac.ir

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