

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effects of β -D-Mannuronic acid with Placebo on disease activity and inflammatory markers in patients with Rheumatoid Arthritis

Protocol summary

Summary

The main target of this study is to assess the safety and efficacy of β -D-Mannuronic acid in patients suffering from Rheumatoid Arthritis. β -D-Mannuronic acid which is an anti-inflammatory agent, is ranked in the family of nonsteroidal anti-inflammatory drugs. This agent has expressed qualified therapeutic effects with the greatest tolerability and safety in different experimental models like experimental model of Multiple sclerosis, Rheumatoid arthritis, nephrotic syndrome and acute glomerulonephritis. In this randomized controlled trial, 203 patients afflicted by Rheumatoid Arthritis, diagnosed based on the American College of Rheumatology (ACR) Diagnostic Criteria that have active disease, will be examined. Furthermore, these patients should not have other concomitant diseases such as Hepatic, renal, cardiovascular diseases or malignancies. Written informed consent will be signed by the patients. Then Patients will be randomly divided into two groups (Treatment and Control group). Treatment group (112 patients) will receive β -D-Mannuronic acid 1500 mg/day (three 500 mg tablets/day) with conventional immunosuppressive drugs and Control group (91 patients)) will receive placebo with conventional immunosuppressive drugs orally for 12 weeks. Medical history and clinical parameters including the serum level of CRP, ESR, RF and Anti CCP will be evaluated at baseline and 12 weeks after treatment. The manner of blinding in this study is so neither participants in the study nor the persons who perform the test will be aware of the intervention. In order to allocate the patients randomly into two groups mentioned above, at first 29 blocks of 7 with C and T letters (The letters indicate the Treatment and Control groups) are created. 4 patients of each block belong to the treatment group and 3 patients belong to the control group. Then the blocks are randomly selected and arranged to reach a sequential combination of 203 letters. Each letter will be placed in a sealed packet according to the obtained sequence

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100213739N10**

Registration date: **2017-11-02, 1396/08/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-02, 1396/08/11

Registrant information

Name

Abbas Mirshafiey

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 4913

Email address

mirshafiey@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-10-16, 1396/07/24

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of β -D-Mannuronic acid with Placebo on disease activity and inflammatory markers in patients with Rheumatoid Arthritis

Public title

Evaluation of the therapeutic efficacy of Mannuronic Acid in Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Patients should be 18-65 year old, afflicted by Rheumatoid Arthritis, diagnosed based on the American College of Rheumatology (ACR) Diagnostic Criteria by a rheumatology specialist after evaluating the clinical parameters such as ESR, RF, CRP and Anti-CCP. 2. Each patient must sign written informed consent. 3. The disease in all patients should be in active form (DAS28 > 2.6) 4. None of patients must suffer from another concomitant diseases like Hepatic, renal, haematological, gastrointestinal, endocrine, cardiovascular, pulmonary, neurological or cerebral diseases. Exclusion Criteria: 1. History of fever and Infectious diseases, positive pregnancy test or lactation, other collagen-vascular diseases, other auto-immune diseases and Malignancies. 2. Enrolling in another clinical trial study within last 4 weeks 3. Suffering from other concomitant diseases such as hepatic, renal, hematological, gastrointestinal, endocrine, cardiovascular, pulmonary, neurological or cerebral disease.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **203**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In order to allocate the patients randomly into two groups of treatment and control, at first 29 blocks of 7 with C and T letters (The letters indicate the intervention and control groups) are created in each 4 patients are belonged to the intervention group and 3 patients are belonged to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 203 letters. Each letter will be placed in a sealed packet according to the obtained sequence.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences-Mashhad-Iran

City

Mashhad

Postal code

-

Approval date

2017-09-06, 1396/06/15

Ethics committee reference number

IR.MUMS.fm.REC.1396.309

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

Morning stiffness

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Taking history and Questionnaire

2

Description

The number of swollen joints

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Examination

3

Description

Pain

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Examination

4

Description

Severity of disease

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Taking history and Questionnaire

Secondary outcomes

1

Description

Serum level of CRP

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Turbidometry

2

Description

level of ESR

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

See through Westergren method

3

Description

Anti-cyclic Citrullinated Peptide (anti-CCP) Antibodies

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

ELISA

4

Description

Rheumatoid factor (RF)

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

See through Agglutination

Intervention groups

1

Description

The Treatment group will receive β -D-Mannuronic acid 1500 mg/day (three oral 500 mg tablets/day) which is produced from the decomposition of Alginate powder (a safe and natural substance used in food and pharmaceutical industries) for 12 weeks. It should be mentioned that Alginate powder is purchased from Sigma Corporation of U.S.A and β -D-Mannuronic acid is produced from its decomposition in central laboratory of immunology department at School of Public Health and Institute of Health Research affiliated by Tehran University of Medical Sciences.

Category

Treatment - Drugs

2

Description

The control group will receive orally 1500 mg/day (three 500 mg tablets/day) of placebo for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology research center, Mashhad University of Medical Sciences

Full name of responsible person

Dr Zahra Rezaee Yazdi-Professor

Street address

Ghaem Hospital, Ahmad abad st, Doctor shariati sq

City

Mashhad

2

Recruitment center

Name of recruitment center

Rheumatology research center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Arman Ahmadzadeh-Assistant Professor

Street address

Loghman-e-Hakim Hospital, Makhsous st, Lashgar crossroad

City

Tehran

3

Recruitment center

Name of recruitment center

Rheumatology research center, Yazd University of Medical Sciences

Full name of responsible person

Dr Soleymani-Associate Professor

Street address

Shahid Sadooghi Hospital, Ebnesina st, Shahid Ghandi Boulevard

City

Yazd

4

Recruitment center

Name of recruitment center

Rheumatology research center, Eslam abad University of Medical Sciences

Full name of responsible person

Dr Abid farooghi-Professor

Street address

G8/3 sector, Loghman hakim st

City

Eslam abad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Younesian (MD, PhD, Vice-Chancellor for Research, Tehran University of Medical Sciences)

Street address

6th floor, central building of Tehran University of Medical Sciences, On the Corner of Keshavarz Blvd. and Qods Street, Keshavarz Blvd., Tehran, Iran

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

Department of pathobiology, School of Public Health, Tehran University of Medical Sciences

Full name of responsible person

Dr. Abbas Mirshafiey

Position

Immunology PHD, Master of Immunology department in public health school

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Immunology PHD

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of pathobiology, School of Public Health, Tehran University of Medical Sciences

Full name of responsible person

Mona Aslani-Saeide Omidian

Position

Msc student in Immunology

Other areas of specialty/work

Street address

Department of Immunology, School of Public Health, Tehran University of Medical Sciences, 16 Azar St, Enghelab Sq, Tehran, Iran

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saiedeomidian1@gmail.com

Web page address

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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