

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effects of α -L-Guluronic acid with conventional Non-steroidal anti-inflammatory drugs on disease activity and inflammatory markers in patients with Rheumatoid Arthritis

Protocol summary

Summary

The aim of this study is to assess the safety and effectiveness of α -L-Guluronic acid in patients with Rheumatoid Arthritis. α -L-Guluronic acid an anti-inflammatory agent that belongs to the family of nonsteroidal anti-inflammatory drugs. This drug has shown therapeutic effects with the greatest tolerability and safety in various experimental models such as experimental model of MS, rheumatoid arthritis, nephrotic syndrome and acute glomerulonephritis. In this randomized, controlled trial, thirty-six patients with Rheumatoid Arthritis fulfilling the American College of Rheumatology Diagnostic Criteria that have the active disease will be examined. Additionally, patients do not have other concomitant diseases (Hepatic, renal and cardiovascular) or malignancies. Written informed consent will be obtained. Patients will be randomly assigned to receive either α -L-Guluronic acid (treatment group, 24 patients) 1500 mg/day (three 500 mg tablets/day) or immunosuppressive drugs (control group, 12 patients) orally for 12 weeks. Medical history, clinical parameters, the serum level of CRP, ESR, RF, Anti CCP will be evaluated at baseline and 12 weeks after treatment. The method of blinding in this study is so neither patients participated in the study nor the persons who perform the test will aware of the intervention. In order to allocate the patients randomly into two groups of treatment and control, at first 6 blocks of 6 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 2 patients are belonged to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 36 letters. Each letter will be placed in a sealed packet according to the obtained sequence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092813739N5**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

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

2016-11-05, 1395/08/15

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of α -L-Guluronic acid with conventional Non-steroidal anti-inflammatory drugs on disease activity and inflammatory markers in patients with Rheumatoid Arthritis

Public title

The therapeutic effects of α -L-Guluronic acid in patients with Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 25-60 years old patients, Diagnosed with RA according to American College of Rheumatology Diagnostic Criteria after the initial visit by a specialist in rheumatology and parameters ESR, RF, CRP and Anti-CCP elected, Each patient must sign written informed consent. Exclusion Criteria: History of fever and Infectious diseases, Positive pregnancy test or Lactation, Other collagen- vascular diseases, Other auto-immune diseases, Malignancies, Patients have enrolled another clinical trial study within last 4 weeks, Other concomitant diseases (Hepatic, renal, haematological, gastrointestinal, endocrine, cardiovascular, pulmonary, neurological or cerebral disease).

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **36**

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 6 blocks of 6 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 2 patients are belonged to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 36 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 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

Postal code**Approval date**

2016-09-14, 1395/06/24

Ethics committee reference number

IR.TUMS.VCR.REC.1395.621

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 intervention group will receive 1500 mg/day (three 500 mg tablets/day) of α -L-Guluronic acid orally for 12 weeks. The α -L-guluronic acid produced from the decomposition of Alginate powder (a safe, natural substance used in food and pharmaceutical industries) purchased from Sigma Corporation of U.S.A, in central laboratory of immunology department of School of Public Health and Institute of Health Research of Tehran University of Medical Sciences.

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology research center, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahdi Mahmoudi (PhD- Assistant Professor)

Street address

Rheumatology research center, Dr.Shariati Hospital, Jalal-e-Al-e-Ahmad St, North Kargar St, Tehran, Iran

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. 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

Head of the Department of pathobiology (PHD -
Professor)

Other areas of specialty/work**Street address**

Department of pathobiology, School of Public Health,
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Web page address

Person responsible for updating data

Contact

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

Person responsible for scientific 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