

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effects of $\alpha$ -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  $\alpha$ -L-Guluronic acid in patients with Rheumatoid Arthritis.  $\alpha$ -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  $\alpha$ -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  $\alpha$ -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  $\alpha$ -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  $\alpha$ -L-Guluronic acid orally for 12 weeks. The  $\alpha$ -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**

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**Web page address**

## 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**

## 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*