Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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+98 21 8895 4913

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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 plcebo 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, Tehran University of Medical Sciences,16 Azar St ,Enghelab Sq, Tehran, Iran

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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

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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