Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ankylosing spondylitis

Protocol summary

Summary

The aim of this study is to assess the safety and effectiveness of α-L-Guluronic acid in patients with Ankylosing spondylitis. α-L-Guluronic acid has shown therapeutic effects with the greatest tolerability and safety in various experimental models such as experimental autoimmune encephalitis, adjuvant induced arthritis, nephrotic syndrome and acute glomerulonephritis. In this randomized, controlled trial, thirty five patients with Ankylosing spondylitis fulfilling the modified New York criteria that have active disease (BASDAI score ≥ 4 and BASFI score ≥ 4) 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, 25 patients) 1500 mg/day (three 500 mg tablets/day) or conventional Non-steroidal anti-inflammatory drugs (control group, 10 patients) orally for 12 weeks. Medical history, physical examinations, BASDAI and BASFI scores, serum level of CRP and level of ESR will be evaluated at baseline and 12 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091813739N4**
Registration date: **2016-10-10, 1395/07/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-10, 1395/07/19

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 ankylosing spondylitis

Public title

The therapeutic effects of α-L-Guluronic acid in patients with ankylosing spondylitis

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Patients aged 18-45 years old; Diagnosis of "Definite AS" as defined by the modified New York criteria; Disease activity equal to BASDAI score ≥ 4; Functional activity equal to BASFI score ≥ 4; 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, hematological, gastrointestinal, endocrine, cardiovascular, pulmonary, neurological or cerebral disease).

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
6th floor, Headquarter for 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
Ankylosing spondylitis

ICD-10 code
M45

ICD-10 code description
Ankylosing spondylitis

Primary outcomes

1

Description
The ASAS20 response criteria

Timepoint
12 weeks after intervention (at the end of study)

Method of measurement
Questionnaire

2

Description
Disease activity

Timepoint
At baseline and after 12 weeks of treatment

Method of measurement
Questionnaire

3

Description
Physical function

Timepoint
At baseline and after 12 weeks of treatment.

Method of measurement
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
Observing with Westegren method

Intervention groups

1

Description
Intervention group will receive 1500 mg/day (three 500 mg tablets/day) of α-L-Guluronic acid orally for 12 weeks.
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, Headquarter for 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, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 8895 4913
Fax
Email
mirshafiey@tums.ac.ir
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
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, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 8895 4913
Fax
Email
mirshafiey@tums.ac.ir
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