Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A randomized controlled trial comparing the effects of β-D-Mannuronic acid and 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 β-D mannuronic acid in patients with Ankylosing spondylitis. β-D mannuronic 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 β-D mannuronic 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, the frequencies of circulating Th17 cells and regulatory T cells, L- selectin expression and leukocyte function-associated antigen-1 (LFA-1) expression will be evaluated at baseline and 12 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062213739N1**
Registration date: **2013-12-30, 1392/10/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-12-30, 1392/10/09

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

1- Vice-Chancellor for Research, Tehran University of Medical Sciences2- Rheumatology research center, Tehran University of Medical Sciences3- Research Center for Immunodeficiencies, Children's Medical Center, Tehran University of Medical Sciences

Expected recruitment start date

2014-04-20, 1393/01/31

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized controlled trial comparing the effects of β-D-Mannuronic acid and conventional Non-steroidal anti-inflammatory drugs on disease activity and inflammatory markers in patients with ankylosing spondylitis

Public title
The therapeutic effects of β-D-Mannuronic acid in patients with ankylosing spondylitis
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion Criteria: Patients age 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, haematological, 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: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
1- In this study the patients and outcomes assessor do not know which β-D mannuronic acid or conventional Non-steroidal anti-inflammatory drugs is being given (double-blind). 2- In this study randomization will be performed by stratified randomization method. 3- β-D mannuronic acid was extracted from Alginic acid sodium salt (Sigma, A2033-1Kg) as a reference sample. This extraction method is a modified procedure of acid hydrolysis method (Chhatbar et al. 2009) that is being performed in Immunology division of Department of pathobiology, School of Public Health, Tehran University of Medical Sciences.

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
2013-10-12, 1392/07/20
Ethics committee reference number
130.1525.92.ص

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

The frequency of circulating Th17 cells

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

flow cytometry

3

Description

The frequency of circulating regulatory T (Treg) cells

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

flow cytometry

4

Description

L- selectin expression

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

flow cytometry

5

Description

LFA-1 expression

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Real-time PCR

6

Description

Serum level of IL-6

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Elisa

7

Description

Serum level of IL-10

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Elisa

8

Description

Serum level of IL-17A

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Elisa

9

Description

Serum level of TNF-α

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Elisa

Intervention groups

1

Description

Treatment group will receive 1500 mg/day (three 500 mg tablets/day) of β-D mannuronic acid orally for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group will receive conventional Non-steroidal anti-inflammatory drugs 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, Tehran University of Medical Sciences, 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

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

2

Sponsor

Name of organization / entity

Rheumatology research center, Tehran University of Medical Sciences

Full name of responsible person

Dr. Ahmad reza Jamshidi (MD, Professor)

Street address

Rheumatology research center, Dr. Shariati Hospital, Tehran University of Medical Sciences, 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

Rheumatology research center, Tehran University of Medical Sciences

Proportion provided by this source

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

3

Sponsor

Name of organization / entity

Research Center for Immunodeficiencies, Tehran University of Medical Sciences

Full name of responsible person

Dr. Asghar Agha Mohammadi (MD, Professor)

Street address

Research Center for Immunodeficiencies, Children's Medical Center, Tehran University of Medical Sciences, 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

Research Center for Immunodeficiencies, Tehran University of Medical Sciences

Proportion provided by this source

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