Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A randomized controlled trial of β, D, Mannuronic acid compared with interferon,beta on clinical signs and symptoms and magnetic resonance imaging (MRI) in multiple sclerosis patients

Protocol summary

Summary

The aim of this study is to assess effectiveness of β, D, mannuronic acid in patients with multiple sclerosis. In this phase 2, randomized controlled trial, thirty six patients with multiple sclerosis have been selected who were injecting different forms ineterferon, beta (interferon beta, 1a and interferon beta, 1b) at least 6 months before the trial. Also, the patients have been chosen among active patients on the basis of disease activity who have had at least one relapsing period during one year or have active lesions in their MRI imaging. From these patients, 24 patients will be randomly assigned to beta, D, mannuronic acid treatment group and will take beta, D, mannuronic 1500 mg/day for 24 weeks (three 500 mg tablets/day), besides interferon beta. Moreover, 12 patients will be assigned randomly to control group and will take different injecting forms of ineterferon, beta (interferon beta, 1a and interferon beta, 1b) and also take placebo for 24 weeks. Additionally, patients do not have other concomitant diseases (hepatic, renal and cardiovascular) or malignancies. Written informed consent will be obtained.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. The study is a single center trial and will be performed on the patients of Iranian Center of Neurological Research in Imam Khomeini hospital, Tehran. Medical history, physical examination and disease activity on MRI imaging will be evaluated by a neurologist before the intervention and 24 weeks after it.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111313739N6**
Registration date: **2017-01-12, 1395/10/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-12, 1395/10/23

Registrant information

Name

Abbas Mirshafiey

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 4913

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mirshafiey@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

1. Vice chancellor for Research, Tehran University of Medical Sciences 2. Iranian Center of Neurological Research

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized controlled trial of β, D, Mannuronic acid compared with interferon,beta on clinical signs and symptoms and magnetic resonance imaging (MRI) in multiple sclerosis patients

Public title

The therapeutic effects of β, D, Mannuronic acid in patients with multiple sclerosis

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion Criteria: 18-60 years old patients, diagnosed with multiple sclerosis who were injecting different forms interferon,beta (interferon beta, 1a, interferon beta, 1b) at least 6 months before the trial. Also, the patients have been chosen by neurologist among active patients on the basis of disease activity who have had at least one relapsing period during one year or have active lesions in their MRI imaging. Written informed consent will be obtained; Exclusion Criteria: History of fever and Infectious diseases, Positive pregnancy test or Lactation, Other collagen vascular diseases, Other autoimmune 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 **60 years** old

Gender

Both

Phase

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

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.

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

City

Tehran

Postal code

Approval date

2016-09-18, 1395/06/28

Ethics committee reference number

IR.TUMS.VCR.REC.1395.632

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Active lesion in MRI imaging

Timepoint

At baseline and after 24 weeks of treatment

Method of measurement

imaging by MRI method

2

Description

the number of relapsing periods

Timepoint

At baseline and after 24 weeks of treatment

Method of measurement

medical history and questionnaire

Secondary outcomes

1

Description
Serum level of IL-6
Timepoint
At baseline and after 24 weeks of treatment
Method of measurement
ELISA test

2

Description
Serum level of TNF-α
Timepoint
At baseline and after 24 weeks of treatment
Method of measurement
ELISA test

3

Description
IL-1β expression
Timepoint
At baseline and after 24 weeks of treatment
Method of measurement
Real-time PCR

4

Description
IL-17 expression
Timepoint
At baseline and after 24 weeks of treatment
Method of measurement
Real-time PCR

Intervention groups

1

Description
The intervention group will receive 1500 mg/day (three 500 mg tablets/day) of Beta, D, Mannuronic acid orally for 24 weeks. The Beta, D, Mannuronic 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 24 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Center of Neurological Research, Imam Khomeini Hospital, Tehran
Full name of responsible person
Dr. Mohammad Hossein Harirchian
Street address
Imam Khomeini Hospital, Keshavarz Blvd.
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
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
Iranian Center of Neurological Research
Full name of responsible person
Dr. Mohammad Hossein Harirchian
Street address
Iranian Center of Neurological Research, Imam Khomeini hospital complex, Keshavarz Blvd.
City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iranian Center of Neurological Research

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

Department of pathobiology (Ph.D, Professor)

Other areas of specialty/work

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Full name of responsible person

Dr. Abbas Mirshafiey

Position

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Other areas of specialty/work

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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