Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of intravenous Trehalose on the fatigue and performance of a patient with Multiple Sclerosis

Protocol summary

Study aim
Investigation the effect of trehalose on fatigue of a patient with MS

Design
This trial is a before-after trial without a control group and will be performed by participation of only one eligible patient.

Settings and conduct
This study will be conducted in Ghaem Hospital in Mashhad. In the current trial, one MS patient who meets the inclusion criteria, will receive IV trehalose (15 gr per week) for 12 weeks. The mentioned outcomes will be compared before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Diagnosis of multiple sclerosis (MS), Suffering from fatigue, Satisfaction for participation in the research project, Living in Mashhad. Exclusion Criteria: Willingness to withdraw from the study, Exacerbation of manifestations of MS after each IV administration, Under treatment of depression.

Intervention groups
Intervention group: IV Trehalose (15 g per week) for 12 weeks by Dr.Rajabi Pharmaceutical Co.

Main outcome variables
Primary outcome: Fatigue Score by Modified Fatigue Impact Scale (MFIS). Secondary outcomes: Quality of life by European Quality of Life 5 Dimensions 3 Level Version (EQ-5D-3L), Depression and Anxiety by Hospital Anxiety and Depression Scale (HADS), Ability to walk by Multiple Sclerosis Walking Scale-12 (MSWS-12), Inflammatory markers including C-reactive protein, gene expression of TNFα, IFNγ, IL10, IL16, IL17). All the mentioned outcomes will be assessed at baseline and after 3 months.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20181022041407N14**
Registration date: **2025-06-19, 1404/03/29**
Registration timing: **prospective**

Last update: **2025-06-19, 1404/03/29**
Update count: **0**

Registration date
2025-06-19, 1404/03/29

Registrant information
Name
Maryam Emadzadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-23, 1404/07/01
Expected recruitment end date
2026-03-21, 1405/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of intravenous Trehalose on the fatigue and performance of a patient with Multiple Sclerosis

Public title

The effect of intravenous trehalose on Fatigue in MS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of multiple sclerosis (MS) Suffering from fatigue Satisfaction for participation in the research project Living in Mashhad

Exclusion criteria:

Willingness to withdraw from the study Exacerbation of manifestations of MS after each IV administration Under treatment for depression

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Mashhad University of Medical Sciences

Street address

Ghoreshi Building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2025-04-26, 1404/02/06

Ethics committee reference number

IR.MUMS.REC.1404.067

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

Multiple S

ICD-10 code description

G35

Primary outcomes

1

Description

Fatigue score

Timepoint

At baseline and after 12 weeks

Method of measurement

Using Modified Fatigue Impact Scale (MFIS)

Secondary outcomes

1

Description

Quality of life

Timepoint

At baseline and after 12 weeks

Method of measurement

Using European Quality of Life 5 Dimensions 3 Level Version (EQ-5D-3L)

2

Description

Depression and anxiety

Timepoint

At baseline and after 12 weeks

Method of measurement

Using Hospital Anxiety and Depression Scale (HADS)

3

Description

Ability to walk

Timepoint

At baseline and after 12 weeks

Method of measurement

Multiple Sclerosis Walking Scale-12 (MSWS-12)

4

Description

Inflammatory markers including C-reactive protein, gene expression of TNFα, IFNγ, IL10, IL16, IL17)

Timepoint

At baseline and after 12 weeks

Method of measurement

Blood Sample

Intervention groups

1

Description
Intervention group: IV Trehalose (15 g per week) for 12 weeks by Dr.Rajabi Pharmaceutical Co.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Maryam Emadzadeh
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Ahmad Abad Blvd., Ghaem Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Maryam Emadzadeh
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
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Person responsible for updating data

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Position
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Specialist

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Public Health/Community Medicine

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available