Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the effect of trehalose on Fatigue in patients with Multiple Sclerosis (MS)

Protocol summary

Study aim
Investigation of the effect of trehalose on Fatigue in patients with Multiple Sclerosis (MS)

Design
Triple-blind parallel randomized clinical trial with control group, on 60 patients.

Settings and conduct
Patients with multiple sclerosis (MS) who will refer to MS clinic of Ghaem Hospital, Mashhad, and met the inclusion criteria, will be enrolled to this study after informed consent. They will be divided randomly into two groups of intervention (trehalose) and control (placebo). The study period is 3 months. The mentioned outcomes will be assessed and compared between two groups at baseline and after 3 months.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:Suffering from multiple sclerosis (MS), At least 6 months under treatment for MS, Age more than 18, Suffering from fatigue, EDSS less or equal to 6, Satisfaction for participation in the research project, Ability to read. Exclusion Criteria: Under treatment of depression.

Intervention groups
Intervention group: 10 gr Trehalose for 12 weeks. Control Group: Placebo (succrose) for 12 weeks.

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). 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: **IRCT20181022041407N8**
Registration date: **2024-08-14, 1403/05/24**
Registration timing: **prospective**

Last update: **2024-08-14, 1403/05/24**
Update count: **0**

Registration date
2024-08-14, 1403/05/24

Registrant information

Name
Maryam Emadzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3882 9262

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2026-09-23, 1405/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of trehalose on Fatigue in patients with Multiple Sclerosis (MS)

Public title

The effect of trehalose on Fatigue in MS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from multiple sclerosis (MS) At least 6 months under treatment Age more than 18 Suffering from fatigue EDSS less or equal to 6 Satisfaction for participation in the research project Ability to read

Exclusion criteria:

Under treatment for depression

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using the block sizes of 2 and 4 with randomization websites such as sealedenvelope.com. After randomization, the type of treatment will be written with odds and even numbers (or A/B codes) in separate papers and placed in an opaque envelope or the paper will be wrapped so that no one can see inside the paper (allocation concealment). After obtaining informed consent from the participants, one paper will be taken in order and according to the noted code, the participants will be placed in one of the intervention or placebo groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After randomization, the patients will be placed in two groups of A/B (or odds/even codes) and will received the products similar in shape and color (blinding of participants). The physician who will give the products to participants, received the boxes of the products with randomized codes (so the physician is blind too). The information of the patients and theirs treatment groups will be written with randomized codes (A/B) (the blinding of the assessor). Data will be entered to the SPSS software with codes (the blinding of the analyzer).

Placebo

Used

Assignment

Parallel

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

2024-06-22, 1403/04/02

Ethics committee reference number

IR.MUMS.REC.1403.133

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

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)

Intervention groups

1

Description
Intervention group: Trehalose 10 g per day for 12 weeks, made by Shaanxi Fruiterco Biotechnology Co.,Ltd.
Category
Treatment - Drugs

2

Description
Control group: Placebo (one sachet of sucrose per day for 12 weeks)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Multiple Sclerosis (MS) Clinic, Ghaem Hospital
Full name of responsible person
Mohammad Ali Nahayati
Street address
Ghaem Hospital, Ahmad Abad Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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 scientific inquiries

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Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutical biotechnology

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Person responsible for updating data

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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