

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effects of probiotics in functional abilities of multiple sclerosis patients: a randomized double-blind placebo-control trial

#### Protocol summary

##### Study aim

Investigating the effects of probiotic supplementation on the functional ability of multiple sclerosis patients

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 90 patients

##### Settings and conduct

In this study, the examiner and the patients will not know the type of received intervention. Patients will be provided with tablets of the same shape in sealed envelopes, and a code (from 1 to 90) will be defined for each of them. Patients will receive one of the interventions randomly. The location of the study will be the Neurology Clinic of Imam Reza Medical Education Center, affiliated to Tabriz University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Definitive diagnosis of multiple sclerosis based on the MacDonald criteria of the 2017 version; RRMS disease type

##### Intervention groups

Patients will be divided into 2 groups: probiotic supplement and placebo. Intervention group: LactoCare probiotic supplement that contains high amounts of 12 beneficial and safe bacterial strains along with fructooligosaccharides as prebiotics. Patients will take this supplement once daily and oral for 4 months. Control group: placebo. This capsule contains an ineffective substance (starch powder) that patients will take once daily for 4 months.

##### Main outcome variables

The measure of physical disability of patients based on the EDSS scale; Gait status of patients; hand function; cognitive findings; fatigue; Psychiatric disorders

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220713055465N1**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

##### Registration date

2022-08-30, 1401/06/08

##### Registrant information

###### Name

Amirreza Naseri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3335 7310

###### Email address

amirx2eza@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-23, 1401/06/01

##### Expected recruitment end date

2023-08-23, 1402/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of probiotics in functional abilities of multiple sclerosis patients: a randomized double-blind placebo-control trial

##### Public title

Probiotic supplementation in multiple sclerosis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Definitive diagnosis of multiple sclerosis based on 2017 MacDonald criteria RRMS Informed consent

### Exclusion criteria:

Lack of consent to continue the study at any stage The presence of other neurological diseases at the same time as MS Diabetes mellitus (DM) Anemia Other inflammatory diseases Rheumatological diseases Acute and chronic infectious diseases (including urinary tract infection) Discopathy Relapsing of the disease in the last 4 months Receiving pulse coronet during the last 4 months Progressive MS CIS (Clinically isolated syndrome) Literacy level below 12 years and lack of proficiency in Persian language Severe depression and use of antidepressants Alcohol or drug abuse Thyroid disorders Taking drugs that affect fatigue Pregnancy

## Age

No age limit

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: 90

## Randomization (investigator's opinion)

Randomized

## Randomization description

Table of random numbers In this method, each person participating in the study is assigned a number (from 1 to 90; according to the sample size) and a subset of the population is randomly selected using a table of random numbers. Even numbers are assigned to the intervention group and odd numbers to the placebo group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The examiner, the patient, and the data analyst will not know the type of intervention the patient received.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

#### Street address

Golgasht

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166/15731

### Approval date

2022-08-01, 1401/05/10

### Ethics committee reference number

IR.TBZMED.REC.1401.426

## 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

Cognitive Impairment

### Timepoint

Baseline and end of treatment period

### Method of measurement

Symbol Digit Modalities Test and Paced Auditory Serial Addition Test

## 2

### Description

Depression

### Timepoint

Baseline and end of treatment period

### Method of measurement

Beck's Depression Inventory

## 3

### Description

Physical disabilities

### Timepoint

Baseline and end of treatment period

### Method of measurement

Expanded Disability Status Scale (EDSS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: LactoCare probiotic supplement that contains high amounts of 12 beneficial and safe bacterial strains along with fructooligosaccharides as prebiotics. Patients will take this supplement once daily and oral for 4 months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: placebo. This capsule contains an ineffective substance (starch powder) that patients will take once daily for 4 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital, Tabriz

##### Full name of responsible person

Mahnaz Talebi

##### Street address

Golgasht

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3334 0730

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##### Email

Talebi511@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz 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

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Mahnaz Talebi

##### Position

Professor

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Neuroscience

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## Person responsible for scientific inquiries

#### Contact

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Professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Amirreza Naseri  
**Position**  
Medical Student  
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A Level or less  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Information on the main outcomes will be reported.

### When the data will become available and for how long

6 months after the results are published

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

The data will be available for use in other studies such as review studies.

### From where data/document is obtainable

Mahnaz Talebi Email: Talebi511@yahoo.com  
Neurosciences Research Center (NSRC), Tabriz University of Medical Sciences, Tabriz, Iran

### What processes are involved for a request to access data/document

Email to correspondence Mahnaz Talebi Email:  
Talebi511@yahoo.com Neurosciences Research Center  
(NSRC), Tabriz University of Medical Sciences, Tabriz,  
Iran

### Comments