

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Fax

+98 41 3334 0730

Email

Talebi511@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahnaz Talebi

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 0730

Fax

+98 41 3334 0730

Email

Talebi511@yahoo.com

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

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 0730

Fax

+98 41 3334 0730

Email

Talebi511@yahoo.com

Person responsible for scientific 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
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 0730
Fax
+98 41 3334 0730
Email
Talebi511@yahoo.com

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
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756

Phone
+98 41 3335 7310
Fax
Email
amirx2eza@gmail.com

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