Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Investigating the effect of probiotic supplementation compared to placebo on serum oxidative stress factors in patients with multiple sclerosis (MS)

Protocol summary

Study aim
determining the effects of probiotic supplementation on the oxidative stress markers of multiple sclerosis patients

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 90 patients. Randomization will be conducted by random numbers table. Each person participating in the study is assigned a number 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.

Settings and conduct
In this study, the examiner and the patients will not know the type of received intervention. 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
Inclusion criteria: patients affected by relapsing remitting MS (RRMS); informed consent. Non-inclusion criteria: The presence of other neurological diseases at the same time as MS; Diabetes mellitus; Anemia; Other inflammatory diseases; Rheumatological diseases; Acute and chronic infectious diseases (including UTI); Discopathy; Relapsing of the disease in the last 4 months; Receiving pulse coronet during the last 4 months

Intervention groups
Intervention group: Patients will take LactoCare probiotic 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
Oxidative stress markers including MDA، SOD، ATC، GSH، GPX1 و GPX2

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220713055465N2**
Registration date: **2023-05-09, 1402/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-09, 1402/02/19**
Update count: **0**

Registration date
2023-05-09, 1402/02/19

Registrant information

Name
Amirreza Naseri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3335 7310

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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
Investigating the effect of probiotic supplementation compared to placebo on serum oxidative stress factors in patients with multiple sclerosis (MS)

Public title
Probiotic supplementation in multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of multiple sclerosis based on 2017 MacDonald criteria Relapsing Remitting MS (RRMS) Informed consent to participate in the study

Exclusion criteria:
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, patient and data analyst will not know the type of intervention received by the patient. Capsules of the same shape containing the placebo or probiotic supplement will be delivered to the patients in identically packaged containers

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
Gogasht

City
Tabriz

Province
East Azarbaijan

Postal code
5166/15731

Approval date
2022-11-21, 1401/08/30

Ethics committee reference number
IR.TBZMED.REC.1401.772

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
Oxidative stress markers including MDA، SOD، ATC، GSH، GPX1 و GPX2

Timepoint
Baseline and end of treatment period

Method of measurement
Based on serum samples of the patients

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

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5166614756

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Talebi511@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Parviz Shahabi

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shahabip@tbzmed.ac.ir

Web page address

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 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

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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