

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of probiotic *Saccharomyces Bulardi* on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis (MS)

Protocol summary

Study aim

Determination of the effect of probiotic *Saccharomyces Bulardi* on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis

Design

This study is a phase-1, 4-month two arm parallel concealed, randomized, double-blind, placebo-controlled clinical trial among 50 participants with multiple sclerosis. Participants will randomly be divided into two groups to take either probiotic supplements (n D 25) or placebo (n D 25).

Settings and conduct

Sampling in this study will be done in a non probable and available way. All participants will be enrolled in the study after description of the methods of study and obtaining written informed consent. General information will be collected using a demographic questionnaire. After taking blood samples from patients and evaluating study variables and randomly entering them into one of two groups, capsules are delivered to people for two weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: multiple sclerosis confirmed by a neurologist; no other chronic diseases; not pregnant; not consuming probiotic foods from a month before the study Exclusion criteria: acute gastrointestinal disease; acute and severe phase of MS

Intervention groups

First, all participants would be matched based on body mass index and age. Participants would be then randomly divided into two groups to take either probiotic supplements (n D 25) or placebo (n D 25) for 4 months. In the intervention group (n D 25), participants will receive a probiotic capsule daily for 4 months. The probiotic capsule are contained *Saccharomyces Bulardi*.

Main outcome variables

mental health; fatigue, quality of life; pain; inflammatory indices (hs-CRP); Oxidative stress (total antioxidant capacity; superoxide dismutase; Malondialdehyde)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N1**

Registration date: **2018-04-09, 1397/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

Registration date

2018-04-09, 1397/01/20

Registrant information

Name

Neda Dolatkahh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 1928

Email address

dolatkahh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic Saccharomyces Bulardi on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis (MS)

Public title

The effect of probiotic Saccharomyces Bulardi in Multiple Sclerosis (MS)

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a disease for more than a year Multiple sclerosis confirmed by a neurologist No other chronic diseases Lack of mental illness Not pregnant Not consuming probiotic foods from a month before the study

Exclusion criteria:

Unwillingness to continue studying at each stage Consumption of any probiotic food during the study Acute gastrointestinal disease Antibiotic use during the study Acute and severe phase of MS

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

1

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomizations will be conducted by an assistant using permuted block randomization method and stratified randomization will be used to match participants based on age and body mass index

Blinding (investigator's opinion)

Triple blinded

Blinding description

It would be impossible for research personnel involving with participants or analyzing the study results to adjust randomization or discern what product participants were receiving, ensuring true allocation concealment. The placebo is indistinguishable in color, smell and taste from the probiotic capsule.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Regional Ethics Committee for Research (Human Subjects Studies) Tabriz University of Medical Science

Street address

Emam Reza Hospital, Golgasht, Azadi Avenue.

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Approval date

2017-10-02, 1396/07/10

Ethics committee reference number

IR.TBZMED.REC.1396.592

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**

mental health

Timepoint

Determining mental health at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

General Health Questionnaire (GHQ-28)

2**Description**

quality of life

Timepoint

Determining quality of life at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

SF-36 quality of life questionnaire

3

Description

pain

Timepoint

Determining pain at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

visual analogue scale

4

Description

fatigue

Timepoint

Determining fatigue at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

fatigue severity scale (FSS)

5

Description

hs-CRP inflammatory index

Timepoint

Determining hs-CRP inflammatory index at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

biochemical assay

6

Description

total antioxidant capacity (TAC)

Timepoint

Determining total antioxidant capacity (TAC) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

biochemical assay

7

Description

superoxide dismutase (SOD)

Timepoint

Determining superoxide dismutase (SOD) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

biochemical assay

8

Description

malondialdehyde (MDA)

Timepoint

Determining malondialdehyde (MDA) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

Method of measurement

biochemical assay

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Probiotic capsule containing 250 mg yeast of *Saccharomyces boulardii* (1010 CFU) and 100 mg of magnesium and lactose stearates daily after a meal, for 4 months manufactured by a TakGene Zist (Tehran, Iran)

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule containing 100 mg of magnesium and lactose stearates daily after a meal, for 4 months manufactured by a TakGene Zist (Tehran, Iran)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Neda Dolatkhan

Street address

Azadi, Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

dolatkahn@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Neda Dolatkhah

Street address

Azadi, Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

dolatkahn@tbzmed.ac.ir

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

Neda Dolatkhah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Azadi, Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

dolatkahn@tbzmed.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Neda Dolatkhah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Physical Medicine and Rehabilitation Dept., Emam Reza Hospital, Golgasht, Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3336 1928

Email

dolatkahn@tbazmed.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Neda Dolatkhah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Physical Medicine and Rehabilitation Dept., Emam Reza Hospital, Golgasht, Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3336 1928

Email

dolatkahn@tbzmed.ac.ir

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