Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of synbiotic product on gut microbiota changes in patients with multiple sclerosis treated with dimethyl fumarate: A randomized, double-blind, placebo-control clinical trial

Protocol summary

Study aim

The effects of synbiotic product on gut microbiota changes in patients with multiple sclerosis treated with dimethyl fumarate: A randomized, double-blind, placebo-control clinical trial

Design

A Phase 3, randomized controlled parallel-group double-blind clinical trial involving 60 patients will be conducted. Randomization will be implemented utilizing a random block design.

Settings and conduct

Patients with MS referred to the MS clinic of Bo Ali Sina Educational Center who meet the inclusion criteria and do not have the exclusion criteria are included in the study and are divided into two groups according to the randomization table and are evaluated for 6 months . The treating doctor, the patient and the evaluator are unaware of the type of therapeutic

Participants/Inclusion and exclusion criteria

Adults over 18 years of age with a recent diagnosis of Multiple Sclerosis or a first attack consistent with high-risk primary clinical syndrome based on the McDonald 2017 criteria, disability due to EDSS less than 4.5, and candidates for dimethyl fumarate were included in the study. Also, people who have received systemic antibiotics in the last month, people who have received probiotic supplements in the last 3 month, people who have received omega-3 and antioxidants in the last month, and people who are pregnant and lactating are included are excluded from study.

Intervention groups

Familact or placebo capsules daily for 6 months

Main outcome variables

Alterations of pathogenic bacteria, Correlation with clinical manifestations of the disease, Adverse effects' profile of immunomodulatory medications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190804044429N12**
Registration date: **2024-07-06, 1403/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-06, 1403/04/16**
Update count: **0**

Registration date

2024-07-06, 1403/04/16

Registrant information

Name

Monireh Ghazaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 6864

Email address

ghazaeianm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2025-08-12, 1404/05/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effects of synbiotic product on gut microbiota changes in patients with multiple sclerosis treated with dimethyl fumarate: A randomized, double-blind, placebo-control clinical trial

Public title
The effects of synbiotic product on gut microbiota changes in patients with multiple sclerosis treated with dimethyl fumarate

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults over 18 years of age with a recent diagnosis of MS or a first attack consistent with a high-risk primary clinical syndrome based on the McDonald 2017 criteria Expanded disability status scale less than 4.5 Candidate for dimethyl fumarate

Exclusion criteria:
Pregnancy Antibiotic use in the past month Consumption of any product and supplement that contains probiotics during the last three months Consumption of omega-3 and other antioxidants during the last month Systemic glucocorticoid use during the last month breastfeeding

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random block method will be used to allocate the samples to two groups. Blocks will be considered as 4 blocks and in each block of 4 people, two people in the intervention group and two people in the control group will be selected. The selection of the order type in each group for each person will be done through second version of random allocation software.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double_ blind. Outcome elevator and participant are blinded (double blind) and aware from grouping (intervention or placebo). Patients will receive either a product containing probiotics or a placebo in identically colored and sized packages. Each package will be assigned a code corresponding to the randomized blocks. Within each block of four individuals, participants will be assigned either the placebo or the active medication. If a severe adverse reaction to the medication occurs, a designated personnel will unblind the relevant patient's code and appropriate treatment measures will be promptly initiated

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Mazandaran University of Medical Sciences

Street address
Ibn Sina hospital, Pasdaran Blvd, Sari town

City
Sari

Province
Mazandaran

Postal code
4816864193

Approval date
2024-04-17, 1403/01/29

Ethics committee reference number
IR.MAZUMS.REC.1403.047

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
Changes in the bacteria in the digestive tract of people with MS

Timepoint
At the beginning of treatment and month 6

Method of measurement
PCR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients are prescribed one Familact (synbiotic) capsule every night following their initial disease diagnosis for a period of six months after their main meal.
Category
Treatment - Drugs

2

Description
Control group: Patients are prescribed one placebo capsule each night following their initial disease diagnosis for a period of six months after their main meal.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina hospital
Full name of responsible person
Monireh Ghazaeian
Street address
Ibn Sina hospital, Pasdaran Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram ebrahimnejad
Street address
Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar three-way, Sari
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Postal code
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Phone
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Email
pajhooheshi@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Monireh Ghazaeian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Data related to the initial outcomes of the study will be shared

When the data will become available and for how long

The data will be available one year after publication

To whom data/document is available

Academic researchers, medical team and scientific institutes

Under which criteria data/document could be used

Requests for sharing data should be sent to the person responsible for general inquiries

From where data/document is obtainable

Requests for sharing data should be sent to the person responsible for general inquiries.
ghazaeianm@gmail.com

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

Principal investigator of the study will reply to the request within 10 days

Comments