Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of beta Hydroxy beta Methyl Butyrate on Disease Progression and Serum Levels of Inflammatory Biomarkers in Patients with Multiple Sclerosis: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Protocol summary

Study aim
Determining the effect of beta-hydroxy-beta-methylbutyrate (HMB) supplementation versus placebo on disease progression and levels of inflammatory biomarkers in patients with multiple sclerosis

Design
A randomized, double-blind, parallel-group, controlled clinical trial with a sample size of 46.

Settings and conduct
Visiting the Khuzestan Province MS Association in the year 1405; selecting 46 patients based on inclusion and exclusion criteria; randomizing them into intervention and control groups; blinding patients and the researcher; and coding performed by a third party unaware of the details

Participants/Inclusion and exclusion criteria
The disease must be diagnosed based on McDonald criteria and MRI findings. The EDSS score must be 5.5 or lower. The patient must have a relapsing-remitting clinical course. The patient's age must be between 18 and 60 years. The patient must not smoke. The patient must not be taking supplements containing HMB, vitamins, fiber, omega-3, antioxidants, or anti-inflammatory agents. The patient must not have any chronic, progressive, or autoimmune diseases.

Intervention groups
Intervention: Daily intake of 3 g of hydroxymethylbutyrate supplement Control: Daily intake of 3 g of placebo

Main outcome variables
Disease severity Fatigue Pain Motor function Handgrip strength

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260922071163N1**
Registration date: **2026-10-03, 1405/07/11**
Registration timing: **prospective**

Last update: **2026-10-03, 1405/07/11**
Update count: **0**

Registration date
2026-10-03, 1405/07/11

Registrant information

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Maryam Parsanahad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01

Expected recruitment end date
2027-02-20, 1405/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of beta Hydroxy beta Methyl Butyrate on Disease Progression and Serum Levels of Inflammatory

Biomarkers in Patients with Multiple Sclerosis: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Public title
beta Hydroxy beta Methyl Butyrate in Multiple Sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis based on McDonald criteria and MRI Relapsing-remitting clinical status EDSS score ≤ 5.5 Both male and female genders Age between 18 and 60 years Signing the informed consent form; full awareness of study objectives, benefits, and risks
Exclusion criteria:
renal issues, hepatic failure, heart failure, rheumatic diseases, diabetes, active cancer, severe or chronic gastrointestinal disorders (e.g., nausea, vomiting, severe diarrhea, or severe stomach pain), and uncontrolled severe psychiatric disorders (e.g., schizophrenia, bipolar disorder type I, or untreated severe depression) use of HMB-containing supplements in the past 3 months use of vitamin, fiber, omega-3, antioxidant, or anti-inflammatory supplements during the 3 weeks prior to the start of the study use of non-steroidal anti-inflammatory drugs (NSAIDs), estrogen, progesterone, diuretics, or corticosteroids inflammatory bowel disease (IBD), rheumatoid arthritis, systemic lupus, type 1 diabetes, and other autoimmune diseases Cigarette smoking Pregnancy, breastfeeding
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are assigned to either the intervention group (HMB) or the placebo group using block randomization with block sizes of six to maintain a balanced number of participants in each group throughout the study. The blocks are generated using the online software at https://www.sealedenvelope.com/randomisation/, and each participant is identified by a unique code. In the presence of significant confounding variables—such as age, gender, or disease severity—stratified randomization is employed. Individuals are first stratified based on the significant variable, followed by block randomization within each stratum. In this study, patients are assigned via block randomization into two groups of 23 participants each, as follows: Group A (Intervention): Daily intake of 3 g of HMB (hydroxymethylbutyrate) supplement Group B (Control): Daily intake of 3 g of placebo
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are assigned to either the intervention group (HMB) or the placebo group using block randomization with block sizes of six to maintain a balanced number of participants in each group throughout the study. The blocks are generated using the online software at https://www.sealedenvelope.com/randomisation/, and each participant is identified by a unique code. Group assignment information is kept in sealed, numbered envelopes to ensure allocation concealment, preventing participants or researchers from knowing the assignment prior to allocation. The study is designed as a double-blind trial; neither the participants nor the researchers administering the supplement/placebo or collecting data will be aware of the group assignments. Only the person responsible for producing and packaging the supplements is aware of the codes and groups and plays no role in data collection or analysis, thereby minimizing the risk of assessor and participant bias.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz. Golestan Boulevard. Jundishapur University of Medical Sciences. Deputy for Research.
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Province
Khouzestan
Postal code
6135715794
Approval date
2026-09-05, 1405/06/14
Ethics committee reference number
IR.AJUMS.REC.1405.266

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

Handgrip Strength

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

Using a hand and claw dynamometer

2

Description

Severity of the disease

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

Assessment of disability severity based on clinical examination (EDSS)

3

Description

Fatigue

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

Score obtained from the FSS questionnaire

4

Description

pain

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

Graduated 0–10 scale (VAS)

5

Description

Motor performance

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

T25FW test completion time (time to walk 25 feet)

Secondary outcomes

1

Description

TNF-α

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

ELISA

2

Description

IL-1

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

ELISA

3

Description

IL-17

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

ELISA

4

Description

TGF-β

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

ELISA

5

Description

IFN-γ

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

ELISA

6

Description

NO

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

Colorimetric reaction (using a kit)

Intervention groups

1

Description
Intervention group: Daily intake of 3 grams of hydroxy methyl butyrate (HMB) supplement for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Daily intake of 3 g of placebo for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khuzestan Province MS Society
Full name of responsible person
Davood Shalilahmadi
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Golestan Street, Ahvaz Jundishapur University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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
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Person responsible for updating data

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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
Personal information will be kept confidential, and results will be presented as aggregated statistics.

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