

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of probiotic and zinc supplementation separately and in combination on reducing the complication of influenza-like syndrome during therapy by beta-interferon in patients with relapsing-remitting multiple sclerosis: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of effect of probiotic and zinc supplementation separately and in combination on reducing the complication of influenza-like syndrome during therapy by beta-interferon in patients with relapsing-remitting multiple sclerosis

Design

This is a randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with relapsing-remitting multiple sclerosis referring to the Imam Khomeini Hospital in Hamadan city during the study period will be enrolled in the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 20 to 40 years old; relapsing-remitting multiple sclerosis; corticosteroid therapy for at least 3 weeks. Exclusion criteria: pregnancy or breastfeeding; receiving influenza vaccine; respiratory infection in the past 2 weeks; using alcohol or opioid drugs in the past 2 months; autoimmune diseases or immunodeficiency syndrome; abdominal surgery; short bowel syndrome; mesenteric Ischemia; history of tuberculosis or AIDS.

Intervention groups

Intervention group 1: Beta-interferon-1a 30 micrograms once a week intramuscular and Beta-interferon-1b 250 micrograms every-other-day subcutaneously for 3 months plus tablet zinc oxide 10 mg daily for 3 months and capsule probiotic 500 mg daily for 3 months. Intervention group 2: Beta-interferon-1a 30 micrograms once a week intramuscular and Beta-interferon-1b 250 micrograms every-other-day subcutaneously for 3 months plus tablet zinc oxide 10 mg daily for 3 months. Intervention group 3: Beta-interferon-1a 30 micrograms

once a week intramuscular and Beta-interferon-1b 250 micrograms every-other-day subcutaneously for 3 months plus capsule probiotic 500 mg daily for 3 months.

Main outcome variables

Primary outcome: influenza-like syndrome; secondary outcome: gastrointestinal complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N375**

Registration date: **2021-01-22, 1399/11/03**

Registration timing: **prospective**

Last update: **2021-01-22, 1399/11/03**

Update count: **0**

Registration date

2021-01-22, 1399/11/03

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic and zinc supplementation separately and in combination on reducing the complication of influenza-like syndrome during therapy by beta-interferon in patients with relapsing-remitting multiple sclerosis: a randomized clinical trial

Public title

Effect of probiotic and zinc supplementation separately and in combination on reducing the complication of influenza-like syndrome during therapy by beta-interferon in patients with relapsing-remitting multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 20 to 40 years old Relapsing-remitting multiple sclerosis Corticosteroid therapy for at least 3 weeks

Exclusion criteria:

Pregnancy or breastfeeding, Receiving influenza vaccine Respiratory infection in the past 2 weeks, Using alcohol or opioid drugs in the past 2 months, Autoimmune diseases or immunodeficiency syndrome, Abdominal surgery, Short bowel syndrome, Mesenteric Ischemia, History of tuberculosis or AIDS, Liver or renal disease or diabetes or hypertension

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the intervention 3. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

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Hamadan

Postal code

6517838695

Approval date

2020-11-29, 1399/09/09

Ethics committee reference number

IR.UMSHA.REC.1399.779

Health conditions studied**1****Description of health condition studied**

Relapsing-remitting multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Influenza-like syndrome

Timepoint

3 months after intervention

Method of measurement

By history taking

Secondary outcomes

1

Description

Gastrointestinal complications (nausea, vomiting, abdominal pain), headache and muscle aches, hot flashes, fever and fatigue

Timepoint

3 months after intervention

Method of measurement

By history taking

Intervention groups

1

Description

Intervention group 1: Beta-interferon-1a 30 micrograms once a week intramuscular and Beta-interferon-1b 250 micrograms every-other-day subcutaneously for 3 months plus tablet zinc oxide 10 mg daily for 3 months and capsule probiotic lactocare 500 mg daily for 3 months

Category

Treatment - Drugs

2

Description

Intervention group 2: Beta-interferon-1a 30 micrograms once a week intramuscular and Beta-interferon-1b 250 micrograms every-other-day subcutaneously for 3 months plus tablet zinc oxide 10 mg daily for 3 months

Category

Treatment - Drugs

3

Description

Intervention group 3: Beta-interferon-1a 30 micrograms once a week intramuscular and Beta-interferon-1b 250 micrograms every-other-day subcutaneously for 3 months plus capsule probiotic lactocare 500 mg daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Clinic

Full name of responsible person

Mehran Fathi

Street address

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mehran Fathi

Position

Pharmacy Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Hamedan University of Medical Sciences

Full name of responsible person

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Position

Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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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