Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

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
Province
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.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3832 1371
Email
mehranfathi1717@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
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
Street address
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
mehranfathi1717@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Nouri
Position
Pharmacologist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
fatemenouri1@gmail.com

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
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.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