Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of Fingolimod with and without probiotic and vitamin E on the liver complications of in patients with relapsing-remitting multiple sclerosis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of Fingolimod with and without probiotics and vitamin E on the liver complications of in patients with relapsing-remitting multiple sclerosis

Design

This is a double-blind randomized clinical trial, phase II, in which 80 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 Clinic in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 40 years, Relapsing-remitting multiple sclerosis, Taking Fingolimod for at least 6 to 9 months, Exclusion criteria: Pregnancy or breastfeeding, Immunodeficiency, History of abdominal surgery, The risk of mesenteric ischemia, History of TB or HIV, Hepatitis and liver disease, Diabetes, Kidney diseases, High blood pressure

Intervention groups

Intervention group 1: Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily and LactoCare probiotic capsule (manufactured by Pardis Technology Park Co.) daily for 2 months Intervention group 2: Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily and Perl Vitamin E 100 units (manufactured by Zahravi Pharmaceuticals Co.) daily for 2 Months Intervention group 3: Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily and LactoCare probiotic capsule (manufactured by Pardis Technology Park Co.) daily and Perl Vitamin E 100 units (manufactured by Zahravi Pharmaceutical Co.) daily for 2 months Control group: Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily for 2 months

Main outcome variables

Primary outcome: Hepatic complication Secondary outcome: Gastric complication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N335**
Registration date: **2020-01-20, 1398/10/30**
Registration timing: **prospective**

Last update: **2020-01-20, 1398/10/30**
Update count: **0**

Registration date

2020-01-20, 1398/10/30

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

2020-04-03, 1399/01/15

Expected recruitment end date
2021-09-22, 1400/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Fingolimod with and without probiotic and vitamin E on the liver complications of in patients with relapsing-remitting multiple sclerosis: a double-blind randomized clinical trial

Public title
Effect of Fingolimod with and without probiotic and vitamin E on the liver complications of in patients with relapsing-remitting multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 20 to 40 years, Relapsing-remitting multiple sclerosis, Taking Fingolimod for at least 6 to 9 months,
Exclusion criteria:
Pregnancy or breastfeeding, Immunodeficiency, History of abdominal surgery or short bowel syndrome, The risk of mesenteric ischemia, History of TB or HIV, Hepatitis and liver disease, Diabetes, Kidney diseases, High blood pressure
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs will be given in coded envelops. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions Thus, the trial will be run as triple-blind
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
2019-12-21, 1398/09/30
Ethics committee reference number
IR.UMSHA.REC.1398.794

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
Hepatic complication
Timepoint
Before and 2 months after the intervention
Method of measurement
With liver function tests (ALT, AST)

Secondary outcomes

1

Description
Gastric complication
Timepoint
Before and 2 months after the intervention
Method of measurement
By taking history

Intervention groups

1

Description
Intervention group 1: Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily and LactoCare probiotic capsule (manufactured by Pardis Technology Park Co.) daily for 2 months
Category
Treatment - Drugs

2

Description
Intervention group 2:Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily and Perl Vitamin E 100 units (manufactured by Zahravi Pharmaceuticals Co.) daily for 2 Months
Category
Treatment - Drugs

3

Description
Intervention group 3:Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily and LactoCare probiotic capsule (manufactured by Pardis Technology Park Co.) daily and Perl Vitamin E 100 units (manufactured by Zahravi Pharmaceutical Co.) daily for 2 months
Category
Treatment - Drugs

4

Description
Control group:Fingolimod capsule 0.5 mg (manufactured by Razavi Pharmaceutical Co.) daily for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Clinic in Hamadan city
Full name of responsible person
Fatemeh Ahmadi
Street address
Imam Khomeini Clinic, Mirzadeh Eshghi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Fatemeh Ahmadi
Position

Student of Pharmacy

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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