Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Cichorium intybus and N-acetylcysteine versus placebo on the reduction of liver complications of Fingolimod in patients with multiple sclerosis: a double-blind randomized clinical trial

Protocol summary

Study aim
To compare the effect of Cichorium intybus and N-acetylcysteine versus placebo on the reduction of liver complications of Fingolimod in patients with multiple sclerosis

Design
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Sina Hospital in Hamadan city on 63 eligible patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65 years; Multiple sclerosis; At least 3 weeks after receiving corticosteroids; Exclusion criteria: Pregnancy and lactation; History of tuberculosis, AIDS, hepatitis, diabetes, kidney failure, or hypertension

Intervention groups
Intervention group 1: Tablet Fingolimod 0.5 mg once daily plus capsules containing Cichorium intybus extract 250 mg once daily for 4 months Intervention group 2: Tablet Fingolimod 0.5 mg once daily plus capsule containing N-acetylcysteine 1200 mg once daily for 4 months Control group: Tablet Fingolimod 0.5 mg once daily plus placebo capsule once daily for 4 months

Main outcome variables
Primary outcome: Serum levels of liver enzyme (ALT, AST, and bilirubin)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N410**
Registration date: **2021-12-08, 1400/09/17**
Registration timing: **prospective**

Last update: **2021-12-08, 1400/09/17**
Update count: **0**

Registration date
2021-12-08, 1400/09/17

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-31, 1400/10/10

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of Cichorium intybus and N-acetylcysteine versus placebo on the reduction of liver complications of Fingolimod in patients with multiple sclerosis: a double-blind randomized clinical trial

Public title

Comparison of the effect of Cichorium intybus and N-acetylcysteine versus placebo on the reduction of liver complications of Fingolimod in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years; Multiple sclerosis; At least 3 weeks after receiving corticosteroids;

Exclusion criteria:

Pregnancy and lactation; History of tuberculosis, AIDS, hepatitis, diabetes, kidney failure, or hypertension

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **63**

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 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 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 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)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

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

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Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.UMSHA.REC.1400.696

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

Serum levels of liver enzyme (ALT, AST, and bilirubin)

Timepoint

2 and 4 months after the intervention

Method of measurement

through laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:Tablet Fingolimod 0.5 mg once daily plus capsules containing Cichorium intybus extract 250 mg once daily for 4 months

Category

Treatment - Drugs

2

Description
Intervention group 2:Tablet Fingolimod 0.5 mg once daily plus capsule containing N-acetylcysteine 1200 mg once daily for 4 months
Category
Treatment - Drugs

3

Description
Control group:Tablet Fingolimod 0.5 mg once daily plus placebo capsule once daily for 4 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Hamadan city
Full name of responsible person
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Sponsors / Funding sources

1

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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
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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