

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Country

Iran (Islamic Republic of)

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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

City

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Province

Hamadan

Postal code

6517838695

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

Davood Sarmadi Khojasteh

Street address

Sina Hospital, 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. Reza Shokoohi

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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

Davood Sarmadi Khojasteh

Position

Student of Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Latest degree

Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street addressSchool of Public Health, Hamadan University of
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Hamadan

Province**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