

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of Sylmarin versus placebo on the reduction of liver complication of Teriflunomide in patients with multiple sclerosis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of Sylmarin versus placebo on the reduction of liver complication of Teriflunomide 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 drawing of lots to the intervention and control groups. This trial will be double-blinded.

Settings and conduct

This study will be performed in the Neshat Clinic in Hamadan city on 42 eligible patients with multiple sclerosis. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 70 years Multiple sclerosis
Exclusion criteria: Pregnancy or breastfeeding Alcohol consumption Active viral hepatitis or chronic liver disease

Intervention groups

Intervention group: Teriflunomide tablet 14 mg daily plus sylmarin tablet 140 mg twice daily for 2 months Control group: Teriflunomide tablet 14 mg daily plus placebo tablet (starch) twice a day for 2 months

Main outcome variables

Primary outcome: Liver and biliary function tests (including AST, ALT, ALP, bilirubin and GGT)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N467**
Registration date: **2023-04-04, 1402/01/15**

Registration timing: **prospective**

Last update: **2023-04-04, 1402/01/15**

Update count: **0**

Registration date

2023-04-04, 1402/01/15

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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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Sylmarin versus placebo on the reduction of liver complication of Teriflunomide in patients with multiple sclerosis: a double-blind randomized clinical trial

Public title

Effect of Sylmarin versus placebo on the reduction of liver complication of Teriflunomide in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 70 years Multiple sclerosis

Exclusion criteria:

Pregnancy or breastfeeding Alcohol consumption Active viral hepatitis or chronic liver disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 person who performs the randomization will be different from the person who examines the patients, so the person who examines 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

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-10-29, 1401/08/07

Ethics committee reference number

IR.UMSHA.REC.1401.647

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

Liver and biliary function tests (including AST, ALT, ALP, bilirubin and GGT)

Timepoint

Before the intervention and one and two months after the intervention

Method of measurement

By laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Triflunomide tablet 14 mg daily plus silymarin tablet 140 mg twice daily for 2 months

Category

Treatment - Drugs

2

Description

Control group: Triflunomide tablet 14 mg daily plus placebo tablet (starch) twice a day for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neshat Clinic in Hamadan city

Full name of responsible person

Rezvan Norouzi

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh 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

Rezvan Norouzi

Position

Pharmacolog Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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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

Epidemiology

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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