Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Sylimarin 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 Sylimarin 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: Triflunomide tablet 14 mg daily plus silymarin tablet 140 mg twice daily for 2 months Control group: Triflunomide 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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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 Sylimarin 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 Sylimarin 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
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Hamadan
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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

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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
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Position
Pharmacolog Student

Latest degree
Medical doctor

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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