Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Study of the effect of Silimarin on the reduction of liver complications of fingolimod in patients with Relapsing-Remitting Multiple Sclerosis (RRMS)

Protocol summary

Study aim
Study of the effect of Silimarin on the reduction of liver complications of fingolimod in patients with Relapsing-Remitting Multiple Sclerosis (RRMS)

Design
A clinical trial with a control group, with a factorial group, single blind, non-randomized, for 6 months on 48 patients

Settings and conduct
This study will be performed on 48 patients with RRMS receiving Fingolimod for 6 months, referring to Imam Khomeini Clinic of Hamadan city. Patients with RRMS are divided into two groups of 24 people. The first group will receive the Fingolimod alone and the second group will receive, in addition to Fingolimod , a Livergol containing 150mg of Silymarin at a dose of 140 mg once a day. Patients should be checked once for treatment of liver enzymes such as ALT, AST, ALP, and bilirubin, and then for hepatic metabolism of the ALT, AST and ALP enzymes are checked for six months each month.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who have had at least 3 weeks of onset of corticosteroid attack and received corticosteroids with liver enzymes following corticosteroid therapy. New Patients Receive Fingolimod Patients who are taking interferon and Glatiramer are advised to take the Fingolimod, provided they have no liver problem. Expanded Disability Status Scale below three. Exclusion criteria: Pregnant and lactating women Patients who are allergic to Silymarin Patients with previous history of tuberculosis, HIV, hepatitis and liver problems.

Intervention groups
First group: Fingolimod alone Second group: Fingolimod with Livergol Product containing 150 mg Silymarin, once a day

Main outcome variables
liver complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150628022956N7**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **retrospective**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

Registration date
2019-07-02, 1398/04/11

Registrant information

Name
Sara Ataei

Name of organization / entity
Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-21, 1398/02/31

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of Silimarin on the reduction of liver complications of fingolimod in patients with Relapsing-Remitting Multiple Sclerosis (RRMS)

Public title
The effect of salimarin in patients with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have had at least 3 weeks of onset of corticosteroid attack and received corticosteroids with liver enzymes following corticosteroid therapy. New Patients Receive Fingolimod Patients who are taking interferon and Glatiramer are advised to take the Fingolimod, provided they have no liver problem. Expanded Disability Status Scale below three.

Exclusion criteria:
Pregnant and lactating women Patients who are allergic to Silymarin Patients with previous history of tuberculosis, HIV, hepatitis and liver problems.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description
A sample of Fingolimod and Silymarin is packed in similar packaging and pass code. The researcher and the patient and the data collectors and those who evaluate the outcome do not know the contents of the pack and randomly give a patient an example.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of the hamedan University of Medical Sciences

Street address
Hamedan, Pazhoohesh Crossroad, In front of the Luna park, Hamedan University of Medical Sciences

City
Hamedan

Province
Hamadan

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6517838678

Approval date
2019-03-02, 1397/12/11

Ethics committee reference number
IR.UMSHA.REC.1398.166

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

2

Description of health condition studied
Liver disease

ICD-10 code
K76

ICD-10 code description
Other diseases of liver

Primary outcomes

1

Description
liver complications

Timepoint
At the beginning of the study (before the intervention) and 30, 60, 90, 120, 150 and 180 days after taking Silymarin

Method of measurement
Malondialdehyde index with Ohkawa method- Total antioxidant capacity index with FRAP method- Measurement of protein thiol groups with Ellman's Reagent (DTNB)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with multiple sclerosis(RRMS) receiving Fingolimod alone For 6 months
Category
Treatment - Drugs

2

Description
Intervention group: Patients with multiple sclerosis(RRMS) receiving Fingolimod، With Silymarin with a dose of 140 mg once a day for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital in Hamadan
Full name of responsible person
Dr. Hamid Nafisi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of Hamedan University of Medical Sciences
Full name of responsible person
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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
Research Council of 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
Dr. Sara Ataei
Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
1398
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
Use data with source
From where data/document is obtainable
s.ataei@umsha.ac.ir
What processes are involved for a request to access data/document
Request via email
Comments