

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Clinical trial to evaluate the effect of rosuvastatin adjuvant therapy on oxidative stress factors in the treatment of multiple sclerosis

Protocol summary

Study aim

Determining the effect of oral rosuvastatin on serum levels of oxidative stress factors to help treat and reduce disability in patients with multiple sclerosis

Design

This research project is a clinical trial before and after, single , phase 2. 40 patients will be included in the study and will be followed up for 3 months.

Settings and conduct

The study will be performed in Neshat Clinic of Hamadan and Beheshti Hospital of Hamadan (Hamadan University of Medical Sciences). This study will be a before and after clinical trial in which a group of 40 people will receive the interventions and the interventions are the same for everyone.

Participants/Inclusion and exclusion criteria

This study was performed on patients with multiple sclerosis who had a history of at least one year, MRI radiological findings consistent with the clinical diagnosis of multiple sclerosis, patients with LDL cholesterol levels less than 130 mg / dL and no other inflammatory disease. Done. People who take any combination or drug with antioxidant effects other than prescription drugs are not included in the study.

Intervention groups

This study is a before and after study that has only one group and the interventions are the same for everyone. Rosuvastatin 20 mg tablets + standard treatment

Main outcome variables

Serum catalase level, serum superoxide dismutase level, serum thiol level, Expanded Disability Status Scale (EDSS) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210211050323N1**

Registration date: **2021-09-02, 1400/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-02, 1400/06/11**

Update count: **0**

Registration date

2021-09-02, 1400/06/11

Registrant information

Name

Maryam Etminaniesfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1590

Email address

m.etminani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the effect of rosuvastatin adjuvant therapy on oxidative stress factors in the treatment of multiple sclerosis

Public title

The effect of rosuvastatin in multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of multiple sclerosis at least one year ago
Radiographic findings of magnetic resonance imaging (MRI) consistent with the clinical diagnosis of multiple sclerosis
No other concomitant inflammatory disease
Bad cholesterol levels (low-density lipoprotein) less than 130 mg / dL
No pregnancy and lactation
The consistency of the main treatment of patients and the use of a specific type of drug
Do not take medications other than standard treatments for multiple sclerosis that alter the levels of the factors under consideration. Do not use any combination with antioxidant effects in the past month.

Exclusion criteria:

Existing evidence based on increased patient disability
Consumption of any combination or drug with antioxidant effects except prescription drugs
Existence of any cognitive or behavioral disorders that lead to the patient not cooperating.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences , Shahid Fahmideh St. , Hamedan

City

Hamedan

Province

Hamadan

Postal code

6517838687

Approval date

2021-05-15, 1400/02/25

Ethics committee reference number

IR.UMSHA.REC.1400.158

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 Catalase Levels

Timepoint

Before the intervention and 3 months after the start of the intervention

Method of measurement

Spectrophotometry

2

Description

Serum levels of superoxide dismutase

Timepoint

Before the intervention and 3 months after the start of the intervention

Method of measurement

Spectrophotometry

3

Description

Serum thiol level

Timepoint

Before the intervention and 3 months after the start of the intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Expanded Disability Status Scale (EDSS) score

Timepoint

Before the intervention and 3 months after the start of the intervention

Method of measurement

Expanded Disability Status Scale (EDSS) questionnaire

Intervention groups

1

Description

Intervention group: Resvostatin, 20 mg tablets, once daily, for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neshat Clinic of Hamedan University of Medical Sciences

Full name of responsible person

Ali Saghafi

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Isar Rehabilitation Center , Eram Blvd. , Hamedan

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2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Seyed Mehdi Hosseini

Street address

Shahid Beheshti Medical Center, at the beginning of Eram Boulevard, Ghaem Square, Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Saeed Bashirian

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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

Maryam Atminani Esfahani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No additional information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available