

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial to evaluate the effect of rosuvastatin as adjunctive therapy on cytochrome b-245 beta chain (CYBB) gene expression in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effect of oral rosuvastatin on cytochrome b-245 beta chain (CYBB) gene expression to help treat and reduce disability in patients with multiple sclerosis

Design

This research project is a before-after clinical trial, single group, 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 the Neshat Clinic of Hamadan and Beheshti Hospital of Hamadan (Hamadan University of Medical Sciences).

Participants/Inclusion and exclusion criteria

Inclusion criteria: multiple sclerosis patients with a definitive diagnosis by a neurologist; MRI findings consistent with the clinical diagnosis of multiple sclerosis. Exclusion criteria: People who take any combination; or drugs with antioxidant effects other than prescription drugs.

Intervention groups

This study is a before-after study that has only one intervention group; Rosuvastatin 20 mg tablets + standard treatment

Main outcome variables

cytochrome b-245 beta chain (CYBB) gene expression, Expanded Disability Status Scale (EDSS) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210211050323N3**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **prospective**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Maryam Etminaniesfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the effect of rosuvastatin as adjunctive therapy on cytochrome b-245 beta chain (CYBB) gene expression in patients with 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 drugs with antioxidant effects except prescription drugs
The existence of any cognitive or behavioral disorders with an effect on the patient's cooperation

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

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Province

Hamadan

Postal code

6517838687

Approval date

2021-11-27, 1400/09/06

Ethics committee reference number

IR.UMSHA.REC.1400.697

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

Cytochrome b-245 beta chain (CYBB) gene expression

Timepoint

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

Method of measurement

Laboratory

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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

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 scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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