

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical trial to evaluate the effect of rosuvastatin adjuvant therapy on Sirtuin1 gene expression in the treatment of multiple sclerosis

#### Protocol summary

##### Study aim

Determining the effect of oral rosuvastatin on Sirtuin1 gene expression 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 multiple sclerosis patients by a neurologist with a definitive diagnosis. MRI radiological findings are consistent with the clinical diagnosis of multiple sclerosis. , 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

Sirtuin1 gene expression, Expanded Disability Status Scale ( EDSS) score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210211050323N2**

Registration date: **2021-10-07, 1400/07/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-07, 1400/07/15**

Update count: **0**

##### Registration date

2021-10-07, 1400/07/15

##### Registrant information

###### Name

Maryam Etmianiesfahani

###### 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

2021-10-03, 1400/07/11

##### Expected recruitment end date

2021-11-02, 1400/08/11

##### 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 Sirtuin1 gene expression in the treatment of multiple sclerosis

##### Public title

The effect of rosuvastatin in multiple sclerosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Definitive diagnosis of multiple sclerosis by a neurologist  
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  
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**

2021-09-25, 1400/07/03

**Ethics committee reference number**

IR.UMSHA.REC.1400.503

**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**

Sirtuin1 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

**Street address**

Isar Rehabilitation Center , Eram Blvd. , Hamedan

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info\_hmd@isaarcsi.ir  
**Web page address**  
http://hmd.isaarcsi.ir

## 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**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Saeed Bashirian  
**Street address**  
Hamedan University of Medical Sciences , Shahid  
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**Email**  
s\_bashirian@yahoo.com  
**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  
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Medical Pharmacy  
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## **Person responsible for scientific inquiries**

### **Contact**

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## Person responsible for updating data

### Contact

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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