

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of simvastatin on improvement of multiple sclerosis (MS).

Protocol summary

Summary

Objective: Effectiveness of simvastatin on improvement of multiple sclerosis (MS). Design: Double blind, randomized, blocking study. Study population: patients with MS, aged between 18 and 60 years. Inclusion criteria: Relapsing-remitting MS patients; at least 1 relapse in the previous 12 months; more than three lesions on spinal or brain magnetic resonance imaging or both; baseline expanded disability status scale (EDSS) from 0 to 3.5; aged 18-60 years. Exclusion criteria: clinical CIS syndrome, progressive MS, MS patients with acute clinical relapses occurring during the study, drug abuse, renal failure, pregnancy, hepatitis diseases. Sample: 60. Study Intervention: interferon beta-1a and simvastatin . Time of intervention: Six months after entering the intervention. The outcome of the study: All the clinical and immunological variables were measured at the baseline and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112925284N1**

Registration date: **2015-12-06, 1394/09/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-06, 1394/09/15

Registrant information

Name

Fardin Faraji

Name of organization / entity

Assistain profosor

Country

Iran (Islamic Republic of)

Phone

+98 51 3849 9144

Email address

farajif@mumc.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of simvastatin on improvement of multiple sclerosis (MS).

Public title

Effectiveness of simvastatin on multiple sclerosis (MS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Relapsing-remitting MS patients; at least 1 relapse in the previous 12 months; more than three lesions on spinal or brain magnetic resonance imaging or both; baseline expanded disability status scale (EDSS) from 0 to 3.5; aged 18-60 years. Exclusion criteria: clinical CIS syndrome, progressive MS, MS patients with acute clinical relapses occurring during the study, drug abuse, renal failure, pregnancy, hepatitis diseases.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked*No information***Sample size**

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees1**Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City

Arak

Postal code

3819693345

Approval date

2009-06-22, 1388/04/01

Ethics committee reference number

88-69-1

Health conditions studied1**Description of health condition studied**

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes1**Description**

Assay of cell amplification of peripheral blood leukocytes

Timepoint

6 months after entering the intervention

Method of measurement

MTT assay

Secondary outcomes1**Description**

level of cytokines

Timepoint

6 months after entering the intervention

Method of measurement

ELISA

Intervention groups1**Description**

Control group: Received 30 µg interferon beta-1a; intra-muscular injection; for 6-months

Category

Treatment - Drugs

2**Description**

Intervention group: Received 30 µg interferon beta-1a with 40 mg atorvastatin; intra-muscular injection; for 6-months

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Ghods Hospital

Full name of responsible person

Kevan Ghsami

Street address

Ghods Hospital, Phelestin Avenue

City

Arak

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice Chancellor for Research, Arak University of Medical Sciences

Full name of responsible person

Ali Asghar Yaghobi

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Stree

City
Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research, Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Fardin Faraji

Position
Assistant Professor

Other areas of specialty/work

Street address
Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City
Arak

Postal code

Phone
+98 86 3313 6058

Fax

Email
ghazaviali@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Fardin Faraji

Position

Assistant Professor

Other areas of specialty/work

Street address
Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City
Arak

Postal code

Phone
+98 68033136058

Fax

Email
ghazaviali@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Fardin Faraji

Position
Assistant Professor

Other areas of specialty/work

Street address
Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City
Arak

Postal code

Phone
+98 68033136058

Fax

Email
ghazaviali@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty