Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Assistain profosor
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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 committees

1

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 studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Assay of cell amplification of peripheral blood luokocytes
Timepoint
6 months after entering the intervention
Method of measurement
MTT assay

Secondary outcomes

1

Description
level of cytokines
Timepoint
6 months after entering the intervention
Method of measurement
ELISA

Intervention groups

1

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 centers

1

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 sources

1

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
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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