Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effect of atorvastatin on the disease process in patients with multiple sclerosis

Protocol summary

Summary

Multiple sclerosis is an autoimmune disease that affected the central nervous system. The most common way for treatment of disease is the use of immunosuppressive drugs. Atorvastatin is a statin family of drugs which is effective in control of cholesterol synthesis.This study investigated the effect of atorvastatin on the Multiple sclerosis disease process. In this clinical trial study, demographic data were recorded for 60 patients with multiple sclerosis. Patients were divided into two groups. Before treatment, the measurement of immunological parameters at Baseline and MRI were performed. Case group treated for 12 months with 80 mg daily oral atorvastatin. Samples were taken at the end of the study again. At the beginning and end of the study for all patients EDSS and FSS forms were completed. Inclusion criteria: Informed consent for entering the study and Fill out the form informed consent; MS disease Exclusion criteria: Side effects of the drug

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071323184N1**
Registration date: **2015-08-08, 1394/05/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-08, 1394/05/17

Registrant information

Name

Keivan Ghasami

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 918 849 2394

Email address

k.ghasami@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of atorvastatin on the disease process in patients with multiple sclerosis

Public title

The effect of atorvastatin on patients with multiple sclerosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent for entering the study and Fill out the form informed consent; MS disease Exclusion criteria: Side effects of the drug

Age

From **1 year** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak- Sardasht-Arak University of Medical Sciences-Department of Research

City

Arak

Postal code

Approval date

2010-01-25, 1388/11/05

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 (of):generalized

Primary outcomes

1

Description

Cerebellar function

Timepoint

Pretreatment / six months after treatment / one year after treatment.

Method of measurement

Due to physician's viewpoint

2

Description

Visual function

Timepoint

Pretreatment / six months after treatment / one year after treatment.

Method of measurement

Due to physician's viewpoint

3

Description

Sensory function.

Timepoint

Pretreatment / six months after treatment / one year after treatment.

Method of measurement

Due to physician's viewpoint

4

Description

Digestive function - bladder

Timepoint

Pretreatment / six months after treatment / one year after treatment.

Method of measurement

Due to physician's viewpoint

Secondary outcomes

1

Description

Sensitivity to drug

Timepoint

Pretreatment / six months after treatment / one year after treatment

Method of measurement

Due to physician's viewpoint

Intervention groups

1

Description

The control group: There was no intervention and patients had received the routine treatment. The routine treatment was prescribed due to the doctor's viewpoint and based on disease symptoms and the patient's needs and included drugs such as CinnoVex, Betaferon, Baclofen, Amantadine, etc.

Category

N/A

2

Description

The Case group: In case group, patients in addition to routine therapy were treated with oral Atorvastatin 80 mg daily for one year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Ghasami
Street address
Arak Vali Asr Square Valiasr Hospital
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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 Neurology Department
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Dr Ghasami
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Person responsible for updating data

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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