

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of neuroprotective effects of Memantine-Atorvastatin combination regimen with Atorvastatin in patients with ischemic stroke

Protocol summary

2012-12-06, 1391/09/16

Summary

The purpose of this study is to compare neuroprotective effects of Atorvastatin with combination of Atorvastatin and Memantine in adult patients with ischemic stroke. In this randomized, 2-armed parallel group clinical trial, 40 patients will be recruited from department of neurology, Imam Hussein hospital, Tehran, Iran. After randomization of the subject, subjects in group A will receive Atorvastatin 20mg twice daily and subjects in group B will receive Atorvastatin 20mg twice daily and Memantine 20mg three times daily for 5 days and then 20mg daily for 3 months. Primary outcome measures include: Change in matrix metallo-proteinase 2 and -9 from baseline after 3 and 5 days of Atorvastatin compared to combination of Atorvastatin with memantine (time frame: baseline, 3 days and 5 days after intervention). Secondary Outcome Measures: 1- Improvements from baseline scores after 5 days of Atorvastatin compared to combination of Atorvastatin with Memantine on National Institute of Health Stroke Score (time frame: baseline and 5 days after intervention) 2- Improvements from baseline scores after 5 days of Atorvastatin compared to combination of Atorvastatin with Memantine on Barthel index (time frame: baseline, 1 month and 3 months after intervention)

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of neuroprotective effects of Memantine-Atorvastatin combination regimen with Atorvastatin in patients with ischemic stroke

Public title

Neuroprotective effects of Memantine in ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: all patients with stroke exclusion criteria: hemorrhagic stroke; sensitivity to Memantine or Statins; acute or chronic renal failure; acute or chronic

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092910178N2**

Registration date: **2012-12-06, 1391/09/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

hepatic disease; acute MI (<48 hours); autoimmune diseases; administration of Statin or Memantine during 6 months before stroke

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street, Shahid Chamran High Way

City

Tehran

Postal code

Approval date

2012-04-03, 1391/01/15

Ethics committee reference number

90-1-94-8104

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

164

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

matrix metalloproteinase 2

Timepoint

Day 1, 3, 5

Method of measurement

ELISA kits

2

Description

matrix metalloproteinase 9

Timepoint

Day 1, 3, 5

Method of measurement

ELISA kits

Secondary outcomes

1

Description

Barthel index

Timepoint

3 months after ischemic stroke

Method of measurement

Questionnaire

2

Description

mortality

Timepoint

90 days after stroke

Method of measurement

check by phone

3

Description

National Institute for Health Stroke Score (NIHSS)

Timepoint

Days 1 and 5 after stroke

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention: Memantine 20 mg TID plus Atorvastatin 20 mg BID for 5 days then Memantine 10 mg BID and Atorvastatin 40 mg daily for 3 months.

Category

Treatment - Drugs

2

Description

Control: Atorvastatin 20 mg BID for first 5 days and 40 mg daily for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Neurology, Imam Hussein Hospital

Full name of responsible person

Mohammad Sistanizad

Street address

Shahid Madani Street

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

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Full name of responsible person

Tahereh Shams

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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

Shahid Beheshti 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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Full name of responsible person

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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