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

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 metalo-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)

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

2012-12-06, 1391/09/16

Registrant information

Name
Mohammad Sistanizad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8820 0087
Email address
sistanizadm@sbmu.ac.ir

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

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 metaloproteinase 2

Timepoint
Day 1, 3, 5

Method of measurement
ELISA kits

2

Description
matrix metaloproteinase 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
motality

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
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Shams
Street address
Velenjak Street, Shahid Chamran High Way
City
Tehran
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
Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Assistant Professor / Clinical Pharmacy Specialist
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway
City
Tehran
Postal code
Phone
+98 21 8820 0087
Fax
Email
sistanizadm@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Assistant Professor / Clinical Pharmacy Specialist
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway
City
Tehran
Postal code
Phone
+98 21 8820 0087
Fax
Email
sistanizadm@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway
Full name of responsible person
Hamidreza Kafi
Position
Clinical Pharmacist
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Niaesh Highway
City
Tehran
Postal code
Phone
+98 21 8820 0087
Fax
Email
kafihr@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