Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the protective effects of Atorvastatin compared with Atorvastatin- Coenzyme Q10 co-administration on level of GFAP in patients with stroke

Protocol summary

Summary

The aim of this study is to determine the effects of the co-administration of coenzyme Q10 supplement and statins on treatment protocols of ischemic stroke in inflammatory and outcomes level. This is a Quasi experimental study with 30 days follow-up. A total of 60 patients are enrolled in the study, non-randomized dividing into two groups (n=30) including: 1) patients with ischemic stroke, who are only receiving Atorvastatin (40 mg/day) for 30 days. 2) patients with ischemic stroke, who are receiving Atorvastatin and Coenzyme Q10 simultaneously (Q10-300 mg/day) for 30 days. A 5 cc vein blood sample will be taken from patients in admission time, 72 hours and 30 days after ischemia. GFAP protein level will be evaluated by ELIZA method. Both groups will be examined by neurologist in two phases, during admission and after 30 days for neurologic tests (NIHSS, MRS, MMSE).Inclusion criteria: patients with ischemic stroke involving the middle cerebral artery, confirmed by computed tomography scanning and clinical symptoms; range of age 50-70 years; not to receive statins continuously before entering the study; not to receive antioxidants (such as vitamin C and E) constantly; not to receive anti-inflammatory drugs (steroids, nonsteroidal anti-inflammatory) constantly. Exclusion criteria: patient's death during the study; lack of patient`s availability to follow-up; no tendency to attend in next follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041731773N1**
Registration date: **2017-06-21, 1396/03/31**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name
Leila Simani
Name of organization / entity
Shahid Beheshti Medical University
Country
Iran (Islamic Republic of)
Phone
+98 21 5102 5582
Email address
l.simani90@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the protective effects of Atorvastatin compared with Atorvastatin- Coenzyme Q10 co-administration on level of GFAP in patients with stroke

Public title

Effect of Atorvastatin and CoQ10 on stroke

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: (patients with ischemic stroke involving the middle cerebral artery, confirmed by computed tomography scanning and clinical symptoms; range of age 50-70 years; not to receive statins continuously before entering the study; not to receive antioxidants (such as vitamin C and E) constantly; not to receive anti-inflammatory drugs (steroids, nonsteroidal anti-inflammatory) constantly; not affected by AIDS and neurodegenerative diseases (e.g. Alzheimer's, Parkinson's, amyotrophic lateral sclerosis, multiple sclerosis); no loss of consciousness level due to any reason except stroke (such as shock, alcohol consumption or intoxication); non-pregnancy; non-epilepsy; patient`s consent).Exclusion criteria: (patient's death during the study; lack of patient`s availability to follow-up; no tendency to attend in next follow-up).
Age
From **50 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This is a Quasi experimental pilote study with 30 days follow-up. A total of 60 patients are enrolled in the study, non-randomized dividing into two groups (n=30) according to admitiion days. Even days for Atorvastatin and Odd days for Atorvastatin and CoQ10 will be allocated.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Daneshjo blv., Evin
City
Tehran
Postal code
Approval date
2017-02-19, 1395/12/01
Ethics committee reference number
IR.SBMU.PHNM.1395.616

Health conditions studied

1

Description of health condition studied
ischemic stroke
ICD-10 code
I63
ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Degree of disability
Timepoint
Admission- After 30 day
Method of measurement
Modified Rankin Scale (MRS)

2

Description
Glial fibrillary acidic protein(GFAP)
Timepoint
admission- 72 houre-after 30 day
Method of measurement
eliza kit

3

Description
Cognitive performance
Timepoint
admission- 72 houre-after 30 day
Method of measurement
Mini-Mental State Examination(MMSE)

4

Description
Motor function and verbal
Timepoint
admission- 72 houre-after 30 day
Method of measurement
National Institutes of Health Stroke Scale(NIHSS)

Secondary outcomes

empty

Intervention groups

1

Description
Atorvastatin = 40 mg/day.oral, Coadministration with CoQ10= 300 mg/day Three times a day. 30 days. oral.
Category
Treatment - Drugs

2

Description
Atorvastatin= 40 mg/day,daily 30 days, oral
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Educational Hospital
Full name of responsible person
Leila Simani
Street address
Loghman Hakim Educational Hospital, South Kargar Ave., Kamali St., Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Sahraei
Street address
Shahid Beheshti University of Medical Sciences, Shahid Erabi St., Yaman St., Shahid Chamran Highway
City
Tehran
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, 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Leila Simani
Position
PhD Neuroscince
Other areas of specialty/work
Street address
Loghman Hakim Educational Hospital, Kamali St., South Kargar Ave.
City
Tehran
Postal code
Phone
+98 21 5102 5582
Fax
+98 21 5541 6130
Email
l.simani90@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Loghman Hakim Educational Hospital
Full name of responsible person
Zahra Sahraei
Position
Pharmacotherapy
Other areas of specialty/work
Street address
Loghman Hakim Educational Hospital, Kamali St, South Kargar Ave
City
Tehran
Postal code
1333635445
Phone
+98 21 5102 5582
Fax
+98 982155416130
Email
l.simani90@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Loghman Hakim Medical Center
Full name of responsible person

Leila Simani

Position

PhD Neurosicence

Other areas of specialty/work

Street address

Loghman Hakim Medical Center, Kamali St, South Kargar Ave,

City

Tehran

Postal code

1333635445

Phone

+98 21 5102 5182

Fax

+98 21 5541 6130

Email

l.simani62@gmail.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