

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 admittiion 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 hours-after 30 day

Method of measurement

eliza kit

3

Description

Cognitive performance

Timepoint

admission- 72 hours-after 30 day

Method of measurement

Mini-Mental State Examination(MMSE)

4

Description

Motor function and verbal

Timepoint

admission- 72 hours-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

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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

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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