

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of atorvastatin and rosuvastatin on serum immune factors in acute ischemic stroke patients

Protocol summary

Study aim

Determination of the effect of atorvastatin and rosuvastatin on serum inflammatory factors and clinical criteria in patients with acute stroke

Design

Among patients with acute ischemic stroke which confirmed by imaging and accept to participate at study (patient or guardian) randomly assigned to two groups, Atorvastatin (40 mg BID) or Rosuvastatin (20mg BID). Among 12 to 24 hours of stroke onset and the 5th day after treatment, two blood sample will take for inflammatory markers and also severity of symptoms will record by NIHSS and MRS at presentation and the day fifth.

Settings and conduct

Location: Emergency department and Neurology ward of Beheshti General Hospital each patient will received a random number to determine its group the patient will unaware of statin type the physician who take care the patient will be unaware of the treatment group and he or she will record the results of examination (one physician will do the examination at onset and day fifth) Blood samples send with a number to lab. and they don't know the groups of treatment.

Participants/Inclusion and exclusion criteria

Patients with acute ischemic stroke Referral in the first 24 hours after the onset of symptoms No recent history of statin use No recent history of immunomodulatory drugs use such as corticosteroids or immunosuppressants No history of previous rheumatic or immunological disease

Intervention groups

Group 1: patients take standard dose of Atorvastatin
Drop 2: patients take maximum dose of Rosuvastatin

Main outcome variables

serum level of ESR,CRP and TNF alpha NIHSS and MRS at first day and after 5 days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181009041286N2**

Registration date: **2021-10-03, 1400/07/11**

Registration timing: **prospective**

Last update: **2021-10-03, 1400/07/11**

Update count: **0**

Registration date

2021-10-03, 1400/07/11

Registrant information

Name

reza Daneshvar kakhki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

daneshvar-r@mail.kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-15, 1400/07/23

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of atorvastatin and rosuvastatin on serum immune factors in acute ischemic stroke patients

Public title

"effect of atorvastatin and rosuvastatin in acute ischemic stroke patients"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute brain ischemic stroke Referral in the first 24 hours after the onset of symptoms No recent history of statin use

Exclusion criteria:

Past history of autoimmune disease or rheumatology diseases Recent drug history of antineoplastic or anti-inflammatory Past history of statin's hypersensitivity

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Serum sample before and after treatment (Hour 12-24 from symptom presentation and day 5)

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Randomization is done by permuted block randomization method, so that first all size of 4 blocks that contain two letters A & B are prepared (6 blocks) and we assign a number from 1 to 6 to each of them. Then, using a table of random numbers, numbers from one to six are selected (80 numbers) and based on the selected random numbers, the corresponding block will be written. Doing so will result in a sequence of 80 letters A and B. Each sample will have a number from 1 to 80 if they enter the study, which will receive codes A and B based on the letter list based on each person's number. This will both randomize and make both groups almost identical.

Blinding (investigator's opinion)

Single blinded

Blinding description

After obtaining consent based on random numbers, patients are divided into atorvastatin and rosuvastatin groups and patients are not studied by the type of treatment received. The examining physician is not aware of the type of medication prescribed during the treatment period. And the patient's blood samples are sent to the laboratory without specifications and with a number

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Beheshtei General Hospital, Pezeshk Ave, Ghotbe Ravandei Blvd

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2021-08-14, 1400/05/23

Ethics committee reference number

IR.KAUMS.REC.1400.030

Health conditions studied

1

Description of health condition studied

Acute ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

TNF alpha

Timepoint

before intervention and the fifth day after intervention

Method of measurement

TNF alpha will be assay by ELISA

2

Description

ESR 1 hour

Timepoint

before intervention and the fifth day after intervention

Method of measurement

Wintrobe method

3

Description

C-reactive protein (CRP)

Timepoint

before intervention and the fifth day after intervention

Method of measurement

Immunoturbidimetry

Secondary outcomes

1

Description

NIHSS: The National Institutes of Health Stroke Scale

Timepoint

before intervention and the fifth day after intervention

Method of measurement

The National Institutes of Health Stroke Scale (NIHSS) is a tool used by healthcare providers to objectively quantify the impairment

2

Description

The Modified Rankin Scale (mRS) measures degree of disability/dependence after a stroke

Timepoint

before intervention and the fifth day after intervention

Method of measurement

a questionnaire used by healthcare providers

Intervention groups

1

Description

Intervention group: Rosuvastatin treatment group in which 40 mg of rosuvastatin is given on the first day and then 20 mg of rosuvastatin every 12 hours for 5 days. The chemical composition of this drug is C22H28FN3O6S.

Category

Treatment - Drugs

2

Description

Intervention group: Atorvastatin treatment group in which 80 mg of atorvastatin on the first day and then 40 mg of atorvastatin every 12 hours for 5 days is prescribed. The chemical composition of this drug is C33H35FN2O5.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti hospital

Full name of responsible person

Reza Daneshvar Kakhki

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Pezesh st., Ghotb e Ravandei ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidreza Banafshe

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healthcenter@kaums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohamad Sadegh Ghafarpour

Position

Resident of neurology

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Reza Daneshvar kakhki

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Hamed Mirzaei

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The information and data obtained from the study will be fully shared after analysis to be used in improving the treatment of patients with acute stroke.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Physicians and other researchers working in academic and scientific institutions

Under which criteria data/document could be used

With the approval of the University Research Council, it will be provided to research groups

From where data/document is obtainable

Vice Chancellor of Research & Technology: Hamid Reza Banafsheh (Ph.D) , Professor in Pharmacology Tel: +98 31 55542999 Fax: +98 31 55575057 E-mail: Research@kaums.ac.ir

What processes are involved for a request to access data/document

Formal request from the Vice Chancellor for Research and Technology of the University to provide information and after obtaining permission to contact the first executor of the project to provide data

Comments