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 Beheshtei 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)

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+98 31 5554 0026

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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 hypersensivity
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 atrostatin and resvastatin 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
Isfehan
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 willbe 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: Rusovastatin treatment group in which 40 mg of rusovastatin is given on the first day and then 20 mg of rusoavastatin 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 Beheshtei hospital
Full name of responsible person
Reza Daneshvar Kakhki
Street address
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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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