Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Atorvastatin on the blood-brain barrier biomarkers in acute intracerebral hemorrhage, a pilot clinical trial.

Protocol summary

Study aim

Evaluation of the effect of Atorvastatin administration on the level of angiogenesis and blood-brain barrier serum markers in the acute phase of intracerebral hemorrhage.

Design

Two arms parallel-group randomized clinical trial with blinded outcome assessment.

Settings and conduct

This study will be carried out after obtaining permission from the ethics committee of Shahid Beheshti University of Medical Sciences and the consent of the head of the neurology department of Loghman Hakim Hospital as a clinical trial on patients with acute ICH. They will be randomly divided into two groups.1. Patients with acute intracerebral hemorrhage who receive oral Atorvastatin 40mg/day 2. Patients with acute intracerebral hemorrhage receive routine treatment. Blood samples will be taken from patients at the time of entry, at the end of the study, and on days 14 and 45.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age < 80 years. Intracerebral hemorrhage confirmed by brain CT scan without contrast. low-density lipoprotein (LDL) level >40 mg/d Exclusion Criteria: Pregnancy. Coma at the time of admission. History of neurodegenerative disorders such as Alzheimer's disease, Multiple sclerosis, Parkinson's disease, previous stroke, and psychological problems. History of brain tumors. Intracerebral hemorrhage due to vascular malformation or coagulation disorders. Intracerebral hemorrhage requires surgical evacuation.

Intervention groups

Patients are randomly divided into two groups: 1. Patients with acute intracerebral hemorrhage who receive oral Atorvastatin 40mg/day 2. Patients with acute intracerebral hemorrhage receive routine treatment.

Main outcome variables

Serum level of Matrix metallopeptidase 9 and Vascular endothelial growth factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141116019971N6**
Registration date: **2022-06-26, 1401/04/05**
Registration timing: **prospective**

Last update: **2022-06-26, 1401/04/05**
Update count: **0**

Registration date

2022-06-26, 1401/04/05

Registrant information

Name

Ehsan Karimi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Atorvastatin on the blood-brain barrier biomarkers in acute intracerebral hemorrhage, a pilot clinical trial.

Public title
Atorvastatin in acute intracerebral hemorrhage.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age < 80 years. Intracerebral hemorrhage confirmed by brain CT scan without contrast. low-density lipoprotein (LDL) level >40 mg/dL.
Exclusion criteria:
Pregnancy. Coma at the time of admission. History of neurodegenerative disorders such as Alzheimer's disease, Multiple sclerosis, Parkinson's disease, previous stroke, and psychological problems. History of brain tumors. Intracerebral hemorrhage due to vascular malformation or coagulation disorders. Intracerebral hemorrhage which requires surgical evacuation.
Age
To **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Block random sampling will be used. In the present study, there are two groups (intervention group and control group). Therefore, four blocks will be used. According to the sample size (92 people in total, 46 in each group), 23 blocks of four will be considered. The random allocation of individuals to the group's understudy will be done as follows: First, there will be 23 envelopes containing four cards with A, B, C, and D Latin letters, the letters A and B will be the intervention group, the letters C and D will be considered as the control group. According to the inclusion criteria, the patients would randomly choose one of the 23 sealed envelopes and select a random card from the inside, which is based on the card's label that determines the allocation of the individual to either of the two study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants and the individual who evaluates the outcome are unaware of the allocation of drugs and placebo. Before starting a medication, it will be explained to each patient that ،they will be treated with a tablet orally. But the patients do not know what medicine they have received. The physician is a neurological assistant who is not involved in the study design, interventions, and specific objectives under study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak street, Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2020-12-29, 1399/10/09
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.826

Health conditions studied

1

Description of health condition studied
Intracerebral Hemorrhage
ICD-10 code
I61.2
ICD-10 code description
Nontraumatic intracerebral hemorrhage in hemisphere, unspecified

Primary outcomes

1

Description
Serum level of Matrix metallopeptidase 9
Timepoint
At the time of admission (before intervention) and after 14 and 45 days of Atorvastatin consumption.
Method of measurement
Blood Sample

2

Description
Serum level of Vascular endothelial growth factor.
Timepoint
At the time of admission (before intervention) and after 14 and 45 days of Atorvastatin consumption.

Method of measurement
Blood Sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Tab Atorvastatin 40 mg per day will be administered for 45 days. In addition, routine medical treatment including antihypertensive drugs will be given to the patients.
Category
Treatment - Drugs

2

Description
Control group: this group only will receive routine treatment for intracranial hemorrhage, including antihypertensive drugs.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Mahtab Ramezani
Street address
Loghman Hakim Hospital, Makhsoos St., Lashkar CUV.
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Postal code
1333631151
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Email
drfsf18@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
Research and Technology Center, Shahid Beheshti University of Medical Sciences,Student Blvd, Velenjak
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1985717443
Phone
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Email
Mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
Tehran University of Medical Sciences
Full name of responsible person
Ehsan Karimialavijeh
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
upon completion of the study, Individual participant data (anonymous) comprising age, gender, pain intensity, and vital signs will be released.
When the data will become available and for how long
Access to the information starts in 2023.
To whom data/document is available
All researchers have the possibility to access the data regardless of the research field.
Under which criteria data/document could be used
There is no specific criteria for data access.
From where data/document is obtainable
To request data access, please contact to Dr Ehsan Karimi. E-mail: drkarimi86@gmail.com, Phone number: 00989122493628, Address: Sina hospital, Imam Khomeini Avenue.
What processes are involved for a request to access data/document
Upon contact, data will be sent by email.
Comments