Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The effect of Atorvastatin administration on the outcome of patients with traumatic brain injury

Protocol summary

Study aim

The aim of this study was to evaluate the effect of atorvastatin administration on the outcome of patients with traumatic brain injury.

Design

Sixty patients with brain injury will be included in the study and will be divided into two groups of intervention and control (including 30 patients in each group) in parallel and randomized groups through a table of random numbers. The blinding in this study will be that the nurse prescribing the drug and evaluating the outcome and analyzing the statistical data will not know which group the patients fall into.

Settings and conduct

This double-blind clinical trial study will be performed in Ahvaz Golestan Hospital. In the intervention group, atorvastatin was administered at a daily dose of 20 mg for 10 days. In the control group, the patient will receive a 20 mg placebo tablet every 12 hours for ten days. The blinding in this study will be that the nurse prescribing the drug and evaluating the outcome and analyzing the statistical data will not know which group the patients fall into.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients with moderate severity GCS = 9-13 and severe GCS = 5-8, Patients with size of brain contusions less than 30 CC according to the initial CT-scan of the brain, No history of taking statins Exclusion criteria: Patients with a score of 4 and GCS 3, Grade IV on primary brain CT scan or brain lesions, Patients with severe damage to other internal organs, or spinal cord injury, History of anticoagulants

Intervention groups

In the intervention group, atorvastatin with a daily dose of 20 mg (manufactured by RAHA Iran) will be prescribed for 10 days. The intervention will begin less than 10 hours after the injury. In the control group, the patient will receive a 20 mg placebo tablet every 12 hours for ten days.

Main outcome variables

Patients' functional recovery rate using GOS and DRS criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210113050023N1**
Registration date: **2021-05-31, 1400/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-31, 1400/03/10**
Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

Esmaeil Alipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3571 5794

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-07-05, 1400/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Atorvastatin administration on the outcome of patients with traumatic brain injury

Public title

The effect of atorvastatin administration on the outcome of patients with traumatic brain injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate (GCS = 9.13) and severe (GCS = 8.5) brain trauma injuries based on GCS score Patients with size of brain contusions less than 30 CC according to the initial CT-scan of the brain No history of statins Patients who arrived at the hospital less than 10 hours after the injury their legal representative (guardian or trustee) will be present to receive the consent

Exclusion criteria:

Patients with GCS scores of 4 and 3 Patients with Grade IV on primary brain scan or CT scan Patients with severe damage to other internal organs or spinal cord injury History of kidney or liver disease Creatine>2.5 mg/dl History of brain tumor, stroke History of infection Previous craniotomy Pregnant and lactating women Patients with systolic blood pressure less than 90 mm Hg History of taking low-molecular-weight anticoagulants such as aspirin, wafarin, or heparin (7 days before hospitalization)

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with brain injury will be selected by census according to the inclusion criteria and randomly divided into two groups A and B using a table of random numbers so that by moving the researcher's hand up and down in the table of random numbers, Even numbers will be assigned to group A (Atorvastatin group) and odd numbers to group B (placebo group).

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the double-blindness of the study, the nurse did not know whether the pill he was giving the patient was a placebo or an Atorvastatin pill (due to the similarity of the two pills), and the nurse who recorded the results was unaware that the patients were in the study or control group. The statistical analyzer was also unaware of the type of grouping and prescriptive judgment. The researcher selected the drug and divided it into containers A and B, respectively, and gave it to the nurse for gavage, so the nurse did not know whether the drug was a placebo or not.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jondishapour University Of Medical Sciences

Street address

Ethics Committee of Ahwaz Jondishapour University Of Medical Sciences, Golestan Blvd., Ahwaz

City

Ahvaz

Province

Khouzestan

Postal code

61357157941

Approval date

2021-01-11, 1399/10/22

Ethics committee reference number

IR.AJUMS.REC.1399.826

Health conditions studied

1

Description of health condition studied

Brain Injury

ICD-10 code

P11.2

ICD-10 code description

Unspecified brain damage due to birth injury

Primary outcomes

1

Description

The score calculated from the GOS benchmark in relation to the patient's life condition

Timepoint

Daily until 3 months later

Method of measurement

GOS criteria

2

Description
The score calculated from the DRS measurement criterion in relation to the patient's state of consciousness and function
Timepoint
Daily until 3 months later
Method of measurement
DRS criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to receiving routine care (daily intake of vitamins C and D and E and regulation of sodium, calcium and potassium electrolytes and daily gavage nutrition) of atorvastatin tablets with a daily dose of 20 mg (made by RAHA Iran) every 12 hours to It will be prescribed for 10 days. The intervention will begin less than 10 hours after the injury.
Category
Prevention

2

Description
Control group: In the control group, in addition to receiving routine care (daily intake of vitamins C and D and E and regulation of sodium, calcium and potassium electrolytes and daily gavage nutrition) placebo 20 mg tablet (administered by the Department of Pharmacy of Ahvaz Jundishapur University of Medical Sciences in the same way Atorvastatin tablets will be taken every 12 hours for ten days.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Esmaeil Alipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghadam
Street address
Vice Chancellor For Research of Ahvaz Jundishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Esmaeil Alipour
Position
Resident
Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

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