Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of low-dose atorvastatin (10 mg) on plasma fibrinogen levels and white blood cell counts in patients with traumatic brain injury

Protocol summary

Study aim

The aim is Studying the effect of low-dose atorvastatin (10 mg) on plasma fibrinogen levels and white blood cell counts in patients with traumatic brain injury.

Design

A 2-arm, parallel-group clinical trial (including groups: A- Atorvastatin 10 mg orally, B- Control receiving standard treatments), double-blind, randomized, phase 3 on 70 patients. Random number generation software is used to assign patients to the two groups.

Settings and conduct

Place of conduct: ICU ward of Bahonar Hospital, Kerman. The drugs will be given orally or via NGT. This study is double-blind, in which both the patient's guardian or legal guardian and the researchers who are responsible for recording the data and evaluating the outcomes are unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of mild to severe traumatic brain injury. Admission to the ICU for at least 72 hours. No use of atorvastatin in the 3 months prior to admission. No history of liver disease or elevated liver enzymes (ALT/AST > 3 times normal). Exclusion criteria: Concomitant use of drugs that interact with atorvastatin . Patients with GCS ≤ 3 History of hypersensitivity to atorvastatin. History of statin-induced myopathy or rhabdomyolysis. TBI due to suicide or non-accidental injuries. Need for emergency surgery other than craniotomy (e.g., abdominal or thoracic surgery). Receiving potent anti-inflammatory drugs in the 7 days prior to the study.

Intervention groups

Intervention group: they will receive standard care for treatment during the hospitalization period, as well as atorvastatin 10 mg orally or via NG tube from the first day of hospitalization until discharge from the ICU (or a maximum of 14 days). Control group: they will receive only standard care for treatment during the hospitalization period.

Main outcome variables

Fibrinogen levels, white blood cell count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250803066738N1**
Registration date: **2025-08-07, 1404/05/16**
Registration timing: **prospective**

Last update: **2025-08-07, 1404/05/16**
Update count: **0**

Registration date

2025-08-07, 1404/05/16

Registrant information

Name

amin Soleimani Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of low-dose atorvastatin (10 mg) on plasma fibrinogen levels and white blood cell counts in patients with traumatic brain injury

Public title

Studying the effect of low-dose (10 mg) lipid-lowering drug administration on plasma levels of coagulation factors and white blood cells in patients with traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of traumatic brain injury (TBI) of mild to severe severity (based on GCS). ICU admission for at least 72 hours (to ensure adequate monitoring). No use of atorvastatin in the 3 months prior to hospitalization. No history of liver disease or elevated liver enzymes (ALT/AST > 3 times normal).

Exclusion criteria:

Concomitant use of drugs that interact with atorvastatin (such as some antibiotics, antifungals). Patients with GCS ≤ 3 History of allergy to atorvastatin or any statin. History of statin-induced myopathy or rhabdomyolysis. TBI caused by suicide or non-accidental injuries (for moral and psychological reasons). Need for emergency surgery other than craniotomy (e.g., abdominal or thoracic surgery). Receiving strong anti-inflammatory medications (such as high-dose corticosteroids) within 7 days prior to the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, a block randomization method with blocks of 4 and an allocation ratio of 1:1 is used to maintain balance between groups. Patient allocation is performed using random number generation software (such as R or SPSS) and recorded in sealed envelopes to ensure allocation concealment. All randomization steps are recorded and reported in accordance with CONSORT guidelines.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was double-blind, meaning that both the patient's legal guardian and the researchers responsible for recording data and evaluating outcomes were unaware of the type of treatment the patients received and the details of the treatment, such as the type of medication used. It is worth noting that the consenter is not aware of the group in which his or her patient is placed, and only the neurosurgeon will be aware of the type of medication and treatment so that he or she can provide appropriate care and respond appropriately in the event of complications or problems.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Afzalipour Hospital - Kerman University of Medical sciences

Street address

Clinical Research Development Unit, Afzalipour Hospital, Kerman University of Medical Sciences, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913911

Approval date

2025-08-04, 1404/05/13

Ethics committee reference number

IR.KMU.AH.REC.1404.094

Health conditions studied

1

Description of health condition studied

traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Fibrinogen level

Timepoint
At the beginning of the study and 14 days later
Method of measurement
Blood test

2

Description
White blood cell count
Timepoint
At the beginning of the study and 14 days later
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: they will receive standard care for treatment during the hospitalization period, as well as atorvastatin 10 mg orally or via NG tube from the first day of hospitalization until discharge from the ICU (or a maximum of 14 days).
Category
Treatment - Drugs

2

Description
Control group: They will only receive standard treatment care during their hospitalization.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar Hospital, Kerman
Full name of responsible person
Shahab Ilka
Street address
Shahid Bahonar Hospital, Qarni Street , Kerman,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Amin Soleimani Mohammadi
Position
Resident
Latest degree
Medical doctor
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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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
At the end of the study, some of the information, including the effect of low-dose atorvastatin (10 mg) administration on plasma fibrinogen levels and white blood cell counts in patients with traumatic brain injury, will be shared with healthcare professionals after de-identification.

When the data will become available and for how long
2 to 6 months after the statistical analysis of the data

To whom data/document is available
Researchers in the field of research and health

Under which criteria data/document could be used
In order to use the results and during the written request

From where data/document is obtainable
Saeed Karamouzian-Email (karamouzian@gmail.com)

What processes are involved for a request to access data/document
Purpose of access and use of data, request to e-mail E-mail to the author, second e-mail in case of no response as a reminder, confirmation of the applicant's identity by the general respondent, sending the documentation file

Comments