Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of low dose oral Atrovastatin on inflammatory factors in patients with Traumatic Brain Injury (TBI)

Protocol summary

Study aim
In this study we will investigate the effect low dose oral Atrovastatin on inflammatory factors in patients with traumatic brain injury

Design
Randomised controlled trial, parallel group design of 60 patients, double blind, single center

Settings and conduct
In this study, patients with traumatic brain injury admitted to intensive care unit of Golestan hospital of Ahvaz will be treated with oral atrovstatin. For blinding, patients and the individual who will select the envelopes and the data recorder will not be aware of the type of envelope grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients age between 18 to 50 years with traumatic brain injury. Exclusion criteria: no consent to participate in the study; allergic reaction to Atrovastatin.

Intervention groups
The treatment group : Patients will receive a tablet of Atorvastatin 20mg daily in 2 week period The control group : Patients will receive a tablet of Placebo daily in 2 week period

Main outcome variables
Patients are evaluated for leukocytosis, Leukocytopenia, duration of mechanical ventilation and hospitalization and level of inflammatory factors in intensive care units.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191016045127N1**
Registration date: **2020-01-12, 1398/10/22**
Registration timing: **prospective**
Last update: **2020-01-12, 1398/10/22**
Update count: **0**

Registration date
2020-01-12, 1398/10/22

Registrant information

Name
Hamid Zarezadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3222 0168

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zarezadeh.h@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-29, 1398/11/09

Expected recruitment end date
2020-03-09, 1398/12/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of low dose oral Atrovastatin on inflammatory factors in patients with Traumatic Brain Injury (TBI)

Public title
Effect of oral Atrovastatin on inflammatory factors in patients with traumatic brain injury

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 to 50 years old Patents with traumatic brain injury
Exclusion criteria:
patient’s lack of consent Having allergy to Atrovastatin

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method is used. Randomization unit is individual and the tool used to randomize is the closed envelope. Inside each envelope is the English letter A or B. Patients fall into the intervention or placebo group according to the word that came out of the envelop.

Blinding (investigator's opinion)
Double blinded

Blinding description
None of the patients and the individual who will select the envelopes, know the type of envelope grouping.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jondishapour University of Medical Sciences

Street address
No. 5, Ahvaz Jondishapour University of Medical Sciences Ave., University Blvd., Ahvaz Town,

City
Ahvaz

Province
Khouzestan

Postal code
6401356874

Approval date
2019-11-08, 1398/08/17

Ethics committee reference number
IR.AJUMS.REC.1398.589

Health conditions studied

1

Description of health condition studied
Traumatic Brain Injury

ICD-10 code
S06.1

ICD-10 code description
Traumatic cerebral edema

Primary outcomes

1

Description
leukocytosis

Timepoint
Days 1, 7, 10 and 15 after treatment

Method of measurement
Blood samples will be taken from patients and the values of White Blood Cells will be recorded in the checklist.

2

Description
Leukocytopenia

Timepoint
Days 1, 7, 10 and 15 after treatment

Method of measurement
Blood samples will be taken from patients and the values of White Blood Cells will be recorded in the checklist.

3

Description
Duration of Mechanical Ventilation

Timepoint
During Intervention

Method of measurement
Day

4

Description
hospitalization

Timepoint
During Intervention

Method of measurement
Day

5

Description
Inflammatory Factors

Timepoint
15 days after treatment

Method of measurement
Blood samples are taken from patients and the amount of inflammatory factors determined in the laboratory and will be recorded in the checklist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive a tablet of Atorvastatin 20mg daily in 2 week period.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive a tablet of placebo daily in 2 week period.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Hamid Zareh Zadeh
Street address
No 5, Farvardin blvd, Golestan highway, Ahvaz Town,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Saeid Ahmad Hosseini
Street address
No. 5, Ahvaz Jondishapour University of Medical Sciences Ave., University Blvd., Ahvaz Town,
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hosseini.a@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research of Ahwaz Jundishapour university of medical science
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Foreign
Category of foreign source of funding
Sponsor: country of origin
Country of origin
IR
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
Hamid Zareh Zadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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No 5, Farvardin blvd, Golestan highway, Ahvaz Town,
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Person responsible for scientific inquiries

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Position
Resident
Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information of the patients studied in our study is completely private and cannot be published

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available