

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 atrovastatin. 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)

###### Phone

+98 61 3222 0168

###### Email address

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 Patients 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**

Khuzestan

**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,

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

610435896

##### Phone

+98 61 3374 3018

##### Email

zarezadeh.h@ajums.ac.ir

## 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,

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

610435896

#### Phone

+98 61 3374 3018

#### Email

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 Ahvaz 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

##### Street address

No 5, Farvardin blvd, Golestan highway, Ahvaz Town,

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

610435896

##### Phone

+98 61 3374 3018

##### Email

zarezadeh.h@ajums.ac.ir

## Person responsible for scientific 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

**Street address**

No 5, Farvardin blvd, Golestan highway, Ahvaz Town,

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

610435896

**Phone**

+98 61 3374 3018

**Email**

zarezadeh.h@ajums.ac.ir

**Person responsible for updating data**

**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

**Street address**

No 5, Farvardin blvd, Golestan highway, Ahvaz Town,

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

610435896

**Phone**

+98 61 3374 3018

**Email**

zarezadeh.h@ajums.ac.ir

**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