

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of oral simvastatin on the outcome of patients with severe traumatic brain injury

Protocol summary

Study aim

Determination of the Effect of Oral Simvastatin on the Outcome of Patients with Severe Traumatic Traumatic injury of the Brain

Design

Patients who are eligible for inclusion criteria are randomly assigned to two groups of 49, which are in addition to daily supplemented therapies for oral simvastatin with a daily dose of 40 mg for 10 days. Another group, in addition to supportive care that has been done so far, is divided into placebo (lactose tablets). How to randomize using randomized code by computer software Assigning patients to groups one and two is done by a researcher who is not aware of the treatment groups. The phase of this study is three.

Settings and conduct

All patients with severe traumatic brain injury who go to Imam Hospital emergency department and have the entry criteria enter this clinical trial study.

Participants/Inclusion and exclusion criteria

Patients with severe brain injury with GCS = 8 and below at the time of referral to the emergency room that have CT scan of hematoma or spastic lesions (except fx) and who are not candidates for surgery and between the ages of 18 and 60 years

Intervention groups

98 patients with traumatic brain damage are included in this study. 49 patients undergo supportive care for patients so far and 49 others are treated with simvastatin in addition to the above.

Main outcome variables

Reduce mortality; reduce hospitalization time; improve clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180802040668N1**

Registration date: **2018-10-25, 1397/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**

Update count: **0**

Registration date

2018-10-25, 1397/08/03

Registrant information

Name

sajad shafiee

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3336 1630

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-08, 1397/07/16

Expected recruitment end date

2018-11-07, 1397/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral simvastatin on the outcome of patients with severe traumatic brain injury

Public title

The effect of oral simvastatin on the outcome of patients

with severe traumatic brain injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with severe traumatic brain injury Non-use of corticosteroids and statins and NSAIDs Not having an allergy to statins Not having a history of autoimmune, cardio, respiratory, neuromuscular, liver or kidney disease
Exclusion criteria:
 Space-occupying lesion in the skull, including hematoma and ... GCS higher than 8 or GCS = 3 on admission Age > 60 and < 18 years Syndrome organ trauma that requires surgical intervention. trauma of the limbs that requires surgical intervention. History of poisoning or drug use sepsis during the first 72 hours of admission

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the method of randomization and sequencing is simple and randomization software, and how it is sequenced in the same way, and the assigned group is not known before the assignment of the individual.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this plan, the main physician and the doctors of this article, as well as the patients involved in this project, health care units and nurses, data analyzers and authors of the article, the safety committee and data monitoring, are double blind. And the doctor who blinds and monitors and collects is aware of the subject.

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mazandaran University of Medical Sciences

Street address

Imam Hospital, Razi Ave, Sari Town

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2018-10-07, 1397/07/15

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.3165

Health conditions studied

1

Description of health condition studied

Severe traumatic brain injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

GCS, APACHE2, ISS

Timepoint

The beginning of the study, Day 3 and Day 10 after starting treatment

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In addition to supportive therapies, daily treatment with simvastatin will be administered at a dose of 40 mg per day for 10 days.

Category

Treatment - Drugs

2

Description

Control group: In addition to the therapies that have been done so far, they will be placed under the placebo (lactose tablet).

Category
Treatment - Drugs

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam hospital
Full name of responsible person
Sajad Shafiei
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Sponsors / Funding sources

1

Sponsor

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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

Sari 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

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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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