Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Assessment of the simvastatin effect on the outcome of patients with brain injuries in ICU

Protocol summary

Summary

In this study, the effect of simvastatin on the outcome of patients with brain injuries will be evaluated. In a randomized, double-blind study, 42 patients with brain injuries will be randomly assigned to one of the following two groups: Group 1 (Control) will receive the placebo, and Group 2 (S) will be administered 80 mg of simvastatin at the first day which followed by 40 mg up until the patients are admitted in ICU. The level of CRP and IL6 will be measured on the first day and 72 hours after the injury. The following data will be recorded by a blinded observer: The number of the Days at which the patients are admitted in ICU, the admission GCS, the discharge GCS, the Date of connecting and disconnecting the patient from the ventilator, the Date of Start and stop of the vasoactive utilage and finally, the patients mortality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305075363N3**
Registration date: **2013-09-21, 1392/06/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-21, 1392/06/30

Registrant information

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Taraneh Naghibi
Name of organization / entity
Zanjan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2013-05-01, 1392/02/11

Expected recruitment end date

2014-05-01, 1393/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the simvastatin effect on the outcome of patients with brain injuries in ICU

Public title

Assessment of the simvastatin effect on the outcome of patients with brain injuries in ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: APACHEE score less than 35, age between 18 and 60 years old, patients with brain injuries that scheduled to ICU admission Exclusion criteria:Receiving NSAIDS or corticosteroids, known hypersensitivity to the study drugs, history of cardiac, respiratory, neuromuscular, hepatic or renal diseases, history of brain injuries and pregnancy.

Age

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

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zanjan University of Medical Sciences
Street address
Azadi Blvd.Vice- Chancellor for Research of Zanjan University of Medical Sciences, Zanjan, Iran
City
Zanjan
Postal code
Approval date
2012-11-10, 1391/08/20
Ethics committee reference number
2255/3-3/19

Health conditions studied

1

Description of health condition studied
brain injuries
ICD-10 code
S06.1, S06
ICD-10 code description
Traumatic cerebral oedema, Diffuse brain injury,Focal brain injury,Epidural haemorrhage, Traumatic subdural haemorrhage, Traumatic subarachnoid haemorrhage, Intracranial injury with prolonged coma, Other intracranial injuries, Intracranial injury, unspec

Primary outcomes

1

Description
CRP
Timepoint
first day , 72 h after brain injury
Method of measurement
Kit

2

Description
IL6
Timepoint
first day , 72 h after brain injury
Method of measurement
ELISA Kit

3

Description
The number of admission days in the ICU
Timepoint
The last day of admission in the ICU
Method of measurement
Observation

4

Description
Patient GCS at the first day of admission in the ICU
Timepoint
The first day of admission
Method of measurement
Physical examination

5

Description
Patient GCS at discharge from the ICU
Timepoint
The last day of admission
Method of measurement
Physical examination

6

Description
Time of connecting the patient to the ventilator
Timepoint
Time in which the patient is connected to the ventilator
Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
Group 2 (control) will be administered placebo tablet Contains lactolos until the patients are admitted in the ICU
Category
Treatment - Drugs

2

Description
Group 1 (S) will be administered 80 mg of simvastatin at the first day which followed by 40 mg up until the patients are admitted in ICU
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mosavi Hospital
Full name of responsible person
Dr Taraneh Naghibi
Street address
Mosavi Hospital, Gavazang Blvd, Zanjan, Iran
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice- Chancellor for Research of Zanjan University
Full name of responsible person
Alireza Biglari MD, PhD
Street address
Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences
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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
Vice- Chancellor for Research of Zanjan University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty