

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of atorvastatin on reduction of size of brain contusions and pericontusional edema and prognosis of patients with moderate and severe traumatic brain injury

Protocol summary

Summary

The aim of the current study is to determine effects of atorvastatin in moderate and severe TBI and its role in reduction of size of contusions and pericontusional edema. For this purpose we will include 40 patients with moderate and severe traumatic brain injury (TBI) between 18 to 75 years within 10-hours of injury. Those undergoing surgical evacuation of the hematoma, spinal cord injury and coagulopathy would be excluded from the study. The patients would be assigned to two study groups to receive atorvastatin in a dosage of 20mg every 12 hours for 10 consecutive days or placebo. The Glasgow Outcome Scale (GOS) and GOS-E and Disability Rating scale (DRS) would be assessed after 1, 3 and 6 months of injury. The brain contusion volume and edema would be measured on admission, 5th day and 10th day after the intervention. Clinical scales and size of contusions and pericontusional edema will be compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050920353N2**

Registration date: **2015-08-28, 1394/06/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-28, 1394/06/06

Registrant information

Name

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Name of organization / entity

Neurosurgery Department, Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research of Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2016-06-01, 1395/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of atorvastatin on reduction of size of brain contusions and pericontusional edema and prognosis of patients with moderate and severe traumatic brain injury

Public title

Effects of atorvastatin in patients with traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Documented closed head injury; Age between 18 and 75 years; Having brain contusions on initial brain CT scan; Taking the first dosage of

medication within first 10 hours of trauma event;
GCS:5-13 without influence of sedations upon admission;
Obtaining written informed consent from legally
authorized representative Exclusion criteria: Having a
lesion on brain CT which urges a surgical evacuation at
any time of hospital admission (Surgical EDH, SDH, ICH
or midline shift>5mm and decompressive craniectomy);
Spinal cord injury or spinal column instability with
neurologic deficit; Penetrating brain injury; Any blood
glucose under 50mg/dL or over 500mg/d; Severe renal
disorder from past history or Cr>2.5 or patients on
hemodialysis; Severe liver disease from past history or
total bilirubin above 1.5 times of normal value; INR>1.6;
Systolic BP below 90mmHg on admission without
respond to fluid resuscitation; Pregnant women or a
positive pregnancy test or those who intend to
breastfeed during study days; Associated severe non-
survivable injury; History of previous brain problems
(Tumor, infections, strokes, ...); Usage of warfarin,
heparin, clopidogrel, LMWH within 72 hours prior to
traumatic event

Age

From **18 years** old to **74 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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**

Shiraz University of Medical Sciences

Street address

Zand street, Main building of Shiraz University of
medical sciences, 6th floor,Vice-Chancellor for
Research, Ethics committee in research

City

Shiraz

Postal code

71345-1978

Approval date

2014-07-15, 1393/04/24

Ethics committee reference number

CT-P-9375-7265

Health conditions studied**1****Description of health condition studied**

Brain contusion

ICD-10 code

S06.3

ICD-10 code description

Focal brain injury

Primary outcomes**1****Description**

Brain contusion volume

Timepoint

On admission, day 5 and 10 after intervention

Method of measurement

CT-volumetry of brain contusions

2**Description**

Final outcome(GOS)

Timepoint

6months after intervention

Method of measurement

Glasgow Outcome Scale (GOS) which is from 1 to 5 (1=death, 2=vegetative state, 3=severe disability, 4=moderate disability, 5= good recovery). This is a standard scoring scale for stating final outcome in patients with traumatic brain injury

3**Description**

Volume of pericontusional edema

Timepoint

On admission, day 5 and 10 after intervention

Method of measurement

CT-volumetry of pericontusional edema

Secondary outcomes

empty

Intervention groups**1****Description**

Group 1: Atorvastatin 20 mg tab every 12hours for 10 days

Category

Treatment - Drugs

2

Description

Group 2 : Placebo tablet, 20mg every 12 hours for 10 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei hospital

Full name of responsible person

Nima Derakhshan

Street address

Shahid Chamran Blvd., Shahid Rajaei trauma center and Emtiaz hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Shiraz University of Medical Sciences

Full name of responsible person

Seyed Masoum Masoumpoor

Street address

Zand Blvd.

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor of Research, Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Nima Derakhshan

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Resident of Neurosurgery

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Person responsible for scientific inquiries

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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