Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Simvostatin in moderate traumatic brain injury

Protocol summary

Summary

Traumatic brain injury (TBI) is one of the most common and financially devastating health problems in our society. There are an estimated 1.5 million cases of TBI annually in the United States, with at least 235,000 resultant hospitalizations and approximately 50,000 fatalities per year.1 More than 5 million persons in the United States are TBI survivors. Once the acute care period has ended, many TBI patients are left with motor, cognitive, or emotional dysfunction as a result of their injury.2 Although several therapies have shown benefit in preclinical models, there has been a notable failure of clinical translation, with a large number of late phase II and III trials failing to confirm benefit in human subjects. Thus, the treatment of TBI remains largely supportive, directed toward management of cerebral edema and intracranial hypertension via temporizing measures, such as administration of osmotic agents, hyperventilation, and ventricular drainage.3 None of these interventions have been definitively demonstrated to improve long-term functional outcome.4 The failure of preclinical therapies to translate into clinical benefit may derive from the heterogeneity of TBI pathology, which includes diffuse axonal injury, cerebral contusion, intracerebral hemorrhage (ICH), subarachnoid hemorrhage (SAH), and extraparenchymal hemorrhage. These primary insults are exacerbated by a secondary neuroinflammatory cascade of cerebral hypoperfusion and ischemia, oxidative stress, cerebral edema, and intracranial hypertension. The 3-hydroxy-3-methylglutaryl coenzyme A (HMG CoA) reductase inhibitors, also known as “statins,” are an ideal candidate therapy for acute brain injury. Statins influence multiple mechanisms of acute and secondary neuronal injury; they have endothelial and vasoactive properties, as well as anti-oxidant, anti-inflammatory, anti-excitotoxicity, and anti-thrombotic effects. Statin treatment would be practical to implement in TBI because statins have wide availability, Food and Drug Administration approval, a favorable adverse event profile, and a track record of safety in critically ill populations.Preclinical data supports the benefit of statins in many of these disease processes include brain ischemia ,intracranial hemorrhage, SAH.clinical trials clearly show a benefit of statins in Ischemic stroke, SAH, TBI, alzaimeres pateints. This study investigated the effects of simvastatin in moderate traumatic brain injury to improve GCS,GOS and protection of formation of delayed brain contusion , delayed ischemic lesions and decrease time of hematoma resorption,mortality complication like DVT,Pneumonia. In this study, patients in the randomized groups are divided into (A&B) (Simvastatin and placebo), study done constantly and visited patients on days 1, 3 and 10, discharge time, and at months 1, 3 and 6 the information collected. Patients with a factor of between 8-12 GCS and patients GCS less than 8 and greater than 12 are excluded. Simvastatin dose of 80 mg daily for ten days to patient data and weekly with alkaline phosphate for complication myositis check. The primary outcome include GCS on days 1, 3 and 10 and GOS on mount 1,3,6 Q

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109197597N1**
Registration date: **2011-10-15, 1390/07/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-10-15, 1390/07/23

Registrant information

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Name of organization / entity

Jundishapour medical university

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Recruitment status
Recruitment complete
Funding source
Ahwaz Jundishapour University of Medical Sciences

Expected recruitment start date
2011-01-23, 1389/11/03
Expected recruitment end date
2011-04-21, 1390/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Simvostatin in moderate traumatic brain injury

Public title
Effect of Simvostatin in traumatic brain injury
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion: patients with GCS 8-12 Exclusion: patients with GCS less 8 and more 12
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **66**
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
Ahvaz Jundishapour University of Medical Sciences
Street address
Ahvaz Jundishapour University of Medical Sciences
City
Ahwaz
Postal code
Approval date
2011-01-22, 1389/11/02
Ethics committee reference number
ETH-107

Health conditions studied

1

Description of health condition studied
Traumatic diffuse brain injury
ICD-10 code
S09.9
ICD-10 code description
Unspecified injury of head

Primary outcomes

1

Description
Glascow coma scale (GCS)
Timepoint
Day 1,3,10
Method of measurement
According to GCS score table

2

Description
Glascow outcome scale (GOS)
Timepoint
Mount 1,3,6
Method of measurement
According to GOS score table

Secondary outcomes

1

Description
Myositis
Timepoint
Every weekl alcalin phosphatase
Method of measurement
IU/L

Intervention groups

1

Description
Treatment with Simvastatin 80 mg daily for 10 days with screen Alkp weekly for drug side effect , accumulation of patients information include: GCS at admission and days

3 ,10 and CT scan finding include type and volume of lesions, ischemia and it`s changes , complications like DVT ,Pneumonia and after discharge GOS at mounts 1, 3 , 6 and CT scan finding.

Category

Treatment - Drugs

2

Description

For Placebo use a neuter substance like Simvastatin prepare by pharmacy ward administered for 10 days , accumulation of patients information include: GCS at admission and days 3 ,10 and CT scan finding include type and volume of lesions, ischemia and it`s changes , complications like DVT ,Pneumonia and after discharge GOS at mounts 1, 3 , 6 and CT scan finding.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz golestan hospital

Full name of responsible person

Street address

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Alavi

Street address

Jundishapour Medical University Building ,Research Center

City

Ahwaz

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, Ahvaz Jundishapour 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

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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