

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the effect of Erythropoietin alfa and Placebo on Glasgow Coma Scale Score and Glasgow Outcome Score of the patients with moderate to severe traumatic brain injury

Protocol summary

Summary

This clinical trial is designed to study the effect of erythropoietin alfa in patients with Moderate and severe traumatic brain injury. 70 patients with traumatic brain injury with Glasgow Coma Scale Score of less than 13 and without penetrating head trauma, who are referred to Tehran Shariati hospital, would be classified to Severe (Glasgow Coma Scale Score of less than 9) or moderate (Glasgow Coma Scale Score more than 8 and less than 14) subgroups and then each subgroup randomly (by random block sampling) will be divided to two arms of intervention and Control. In the intervention arms patients will be received 400 IU/Kg Erythropoietin Alfa, intravenously and in Control group 2cc normal saline will be injected as placebo. In both intervention and control arms Glasgow Coma Scale Score would be measured in 24 hours and also seventh day and Glasgow Outcome Scale will be assessed in 6 month. Additionally, hospital stay, mortality and adverse events will be compared in both arms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204149462N1**

Registration date: **2012-06-14, 1391/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-14, 1391/03/25

Registrant information

Name

Anowshiravan Niknezhad

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-05-31, 1388/03/10

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Erythropoietin alfa and Placebo on Glasgow Coma Scale Score and Glasgow Outcome Score of the patients with moderate to severe traumatic brain injury

Public title

The effect of Erythropoietin Alfa in traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion and exclusion Criteria were as follows: Patients with blunt head trauma; GCS equal or less than 13 in admission time; patient admitted in hospital less than 8 hours after trauma Exclusion Criteria: Patient's GCS

above 13 in admission time; patients with GCS=3 and pupils without reaction to light in admission time; penetrating head injury; O2-Sat below 90% in admission time; admission after 8 hours of injury; any critical injury in any part of the body except for head; patient with history of CPR before the intervention; any kind of severe pre-existing systemic co-morbidity; history of hypersensitivity to any injected drug; any patients with drug history of anticoagulant therapy; age under 4 years or above 70 years

Age

From **4 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Research department of tehran university of medical sciences

City

Tehran

Postal code**Approval date**

2012-05-29, 1391/03/09

Ethics committee reference number

91.130.235

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

Traumatic Brain Injury

ICD-10 code

V01-Y98

ICD-10 code description

External causes of morbidity and mortality

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

GCS score

Timepoint

Admission time, 24 hours. 7 days

Method of measurement

Clinical assessment (Physical examination)

Secondary outcomes**1****Description**

Glasgow Outcome Scale Score

Timepoint

6th month

Method of measurement

Clinical assessment (Physical examination)

2**Description**

Decrease in hospital stay

Timepoint

Day of discharge

Method of measurement

days

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

Intervention arms patients will receive 400 IU/Kg Erythropoietin Alfa, intravenously, in a single dose

Category

Treatment - Drugs

2**Description**

Control group will receive 2cc of intravenous normal saline in a single dose

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Dr.Shariati Hospital

Full name of responsible person

Anowshiravan Niknezhad

Street address

Neurosurgery Office, Shariati hospital, Amirabad

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Neurosurgery office, Shariati Hospital, Amirabad

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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

Tehran 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**

Tehran university of medical sciences

Full name of responsible person

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University Professor

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Web page address**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