

# 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

Iran (Islamic Republic of)

##### Phone

+98 21 9922 0040

##### Email address

aniknejad88@razi.tums.ac.ir

##### 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**

Anowshiravan Niknezhad

**Street address**

Neurosurgery office, Shariati Hospital, Amirabad

**City**

Tehran

**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**

Anowshiravan Ninezhad

**Position**

Resident of Neurosurgery

**Other areas of specialty/work****Street address**

Neurosurgery Office, Shariati hospital, Amirabad

**City**

Tehran

**Postal code****Phone**

+98 21 8822 0040

**Fax****Email**

anushnik@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Masood Mehrazin

**Position**

University Professor

**Other areas of specialty/work****Street address**

Neurosurgery office, Shariati hospital, Amirabad

**City**

Tehran

**Postal code****Phone**

+98 21 8822 0040

**Fax****Email**

aniknejad88@razi.tums.ir

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Anowshiravan Niknezhad

**Position**

Neurosurgery Resident

**Other areas of specialty/work****Street address**

Neurosurgery Office, Shariati hospital, Amirabad

**City**

Tehran

**Postal code**

1411713135

**Phone**

+98 21 8822 0040

**Fax**

+98 21 8822 0040

**Email**

anushnik@yahoo.com

**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*