

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of neuroprotective effects of erythropoietin in human traumatic brain injuries

Protocol summary

Summary

Objective: according to recent studies there are some good evidences of neuroprotective effect of erythropoietin. In this study we want to investigate any neuroprotective effect of erythropoietin in traumatic brain injury. Methods: in this double blind controlled randomized clinical trial 50 patients with traumatic brain injury admitted in less than 24 hour time and according to the inclusion/exclusion criteria will be recruited randomly 25 patients in case group will be treated in 3 continuous days with 40000 Unit EPO daily (infusion in 100CC NS in Half an Hour time) and other 25 patient in control group will be infused with NS alone. The time of this trial will be 3 continuous days after the incident initial outcome will be the neurologic status of the patient measured with MMSE and GCS and any morbidity or mortality effect.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110267917N1**

Registration date: **2013-01-18, 1391/10/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-18, 1391/10/29

Registrant information

Name

Hamed Aghdam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3352 3126

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of neuroprotective effects of erythropoietin in human traumatic brain injuries

Public title

Neuroprotective effect of erythropoietin in human traumatic brain injuries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: traumatic brain injury (admit GCS: 9-13); admit less than 24 hour of the incident. Exclusion criteria: every traumatic brain injury with arrival GCS out of range of 9-13; hypoxia (O₂Sat < 90%) without any response to primary airway management procedures such as oxygenation with mask ventilation; any case with operable brain trauma according to initial brain CT Scan or every stage of the hospitalization; any necessity to surgical treatment in any stage of the hospitalization; any past history of cardiologic, renal, pulmonary, and hepatic disorders and also Diabetes Mellitus or severe

symptomatic uncontrolled
Hypertension(SBP>=160mmHg) or MAP < 60 mmHg.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Tehran University of Medical Sciences/medicine
faculty

Street address

six florr/cenral office/cross of Ghods St. and
Keshavarz Blv.

City

Tehran

Postal code

Approval date

2012-06-13, 1391/03/24

Ethics committee reference number

130/304/91/س

Health conditions studied

1

Description of health condition studied

Traumatic Brain Injury

ICD-10 code

S06

ICD-10 code description

Acceleration/deceleration induced Head Trauma

Primary outcomes

1

Description

Mental state (GCS)

Timepoint

As long as patient is admitted or deceased(at most 1
month)(intervals 72 hour,1 week, and 1 month)

Method of measurement

GCS

Secondary outcomes

1

Description

Neurologic exam(Barthel Criteria)

Timepoint

Days 3, 5, 10 and until patient would be discharged or
deseased

Method of measurement

Data recording by a blinded clinician

Intervention groups

1

Description

cases randomlywill be divided into 2 groups of epo
group(treatment group) and control group each recruited
25 patients. in epo group(treatment group) in 3
continuos days the cases will infused with 40000 unit of
erythropoeitin in 100cc NS in 30 min. time.

Category

Treatment - Drugs

2

Description

in the control group patients witch are selected
randomely according to the same inclusion/exclusion
criteria , will be infused with 100 cc NS to perform
blindness.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

The office of Emergency Departement

Street address

Emergency Departement/Sina Hospital/HassanAbad
Square/Imam Khomeini St./Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Assistant of Tehran University Of Medical Sciences

Full name of responsible person

Dr. Akbar Fotohi

Street address

six floor/central office of university/cross Ghods St. and Keshavarz Blvd.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Assistant of 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

Dr. Mohammadreza Yasin Zadeh

Position

Emergency Medicine Specialist/assistant Prof. of Tehran University of Medical Sciences

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

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Person responsible for scientific inquiries

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Position

Emergency Medicine Resident

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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