Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 neurprotective effect of erythropoeitin. In this study we want to investigate any neurprotective effect of erythropoeitin 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 criteriawill be recruited randomly 25 patients in case group will be treated in 3 continuous days with 40000Unit 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 continuos days after the incident initial out come 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

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Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 hospitalizatin; 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 uncontroled
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 florrr/central 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/د

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
Neourologic 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 randomelywill 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
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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