

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of Erythropoietin's effect in patients consciousness with severe Traumatic Brain Injury

Protocol summary

Study aim

Evaluation of Erythropoietin's effect in patients consciousness with severe Traumatic Brain Injury

Design

Randomised, double blinded, controlled clinical trial with parallel groups

Settings and conduct

This Randomised, double blinded, clinical trial is performed in Intensive Care Unit of Sina Hospital in 1397-98. After informed consent patients divided into two groups: intervention and control. Each group contains of 9 patients. In intervention group 24 hours after brain injury 40000 unit Erythropoietin intravenously and then after 8000 unit is injected daily until 2 weeks. In control group patients receive Normal Saline 1 milliliter daily as placebo. Patients consciousness daily via Four Score and Glasgow Coma Score is evaluated and also Length of stay in ICU, mortality and time course to wakefulness is recorded.

Participants/Inclusion and exclusion criteria

Entry requirements: Range of Age between 15-65 years, Traumatic Brain Injury, Level of consciousness equal and less than 9, Hemoglobin less than 18, Mean Arterial Pressure less than 130, Onset of primary Traumatic Injury less than 24 hours, Lack of Venous Thrombosis History, Exit Requirements: Organ Dysfunction, History of Malignancy,

Intervention groups

This study consists of one intervention and one control group which each of them contains of 9 patients. In intervention group 24 hours after brain injury, a loading dose of 40000 unit Erythropoietin intravenously and then after 8000 unit is injected daily until 2 weeks. In control group Normal Saline 1 milliliter is injected daily as placebo.

Main outcome variables

Level of Consciousness; Time course for wakefulness after first Erythropoietin or Placebo injection; Time course after Brain Injury until first Erythropoietin or

Placebo injection; Time course for increasing in Glasgow Coma Score and Four Score after first Erythropoietin or Placebo injection; Incidence of Deep Vein Thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190429043416N1**

Registration date: **2019-06-22, 1398/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-22, 1398/04/01**

Update count: **0**

Registration date

2019-06-22, 1398/04/01

Registrant information

Name

Marjan Lashgari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 0243

Email address

marjan0084@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-14, 1397/11/25

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of Erythropoietin's effect in patients
consciousness with severe Traumatic Brain Injury

Public title
Evaluation of Erythropoietin's effect in patients
consciousness

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Range of Age between 15-65 years Traumatic Brain
Injury(Epidural, Subdural, Intracranial, Intraventricular,
Subarachnoid Hemorrhage, Diffuse Axonal Injury) Level
of consciousness equal and less than 9 Hemoglobin less
than 18 Mean Arterial Pressure less than 130 Onset of
Brain Injury less than 24 hours Lack of History of Venous
Thrombosis
Exclusion criteria:
Organ Dysfunction(Uremic and Hepatic Encephalopathy)
History of Malignancy

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study Simple Randomization is used for random
allocation of samples. For this purpose, referring to Web
Site: www.graphpad/quickcalcs/, we use Random
Allocation Software for randomization in two groups trial.
Sample allocation order is as follows: B=1, A=2, B=3,
B=4, A=5, B=6, B=7, A=8, A=9, A=10, B=11, A=12,
B=13, B=14, A=15, B=16, A=17, A=18

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is Double blinded. Patients, clinical nurses,
researcher and physicians being kept blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Biomedical Research of Tehran
University of Medical Science

Street address

First floor, Building No 1 of school of Medicine, North
Door of Poorsina Ave., Qods Ave., Enghelab Ave

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-02-12, 1397/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.796

Health conditions studied

1

Description of health condition studied

Traumatic Brain Injury

ICD-10 code

S06.899

ICD-10 code description

Other specified intracranial injury with loss of
consciousness of unspecified duration

Primary outcomes

1

Description

Level of Consciousness

Timepoint

Evaluation of level of consciousness in initial of the
study(before intervention) and daily until two weeks after
Erythropoietin injection

Method of measurement

Glasgow Coma Score, Four Score

Secondary outcomes

1

Description

Time course for complete wakefulness after first
Erythropoietin or Placebo injection

Timepoint

Daily until two weeks after Erythropoietin or Placebo
injection

Method of measurement

2

Description

Time course after Brain Injury until first Erythropoietin or Placebo injection

Timepoint

Onset of the study (before injection)

Method of measurement

Nursing Questionary

3

Description

Time course for increasing in Glasgow Coma Score and Four Score after first Erythropoietin or Placebo injection

Timepoint

Daily until two weeks after Erythropoietin or Placebo injection

Method of measurement

Nursing Questionary

4

Description

Incidence of Deep Vein Thrombosis

Timepoint

Daily from first Erythropoietin injection until last injection

Method of measurement

Physical Exam, Doppler Ultra Sonography of lower Extremity

Intervention groups

1

Description

Intervention group: After 24 hours of brain injury 40000 unit of Erythropoietin Ampule via intravenous pathway is injected and patients receive 8000 unit of Erythropoietin intravenously daily until two weeks. Each Erythropoietin Ampule contains 4000 unit (0/5 milliliter) which is prepared from Pooyesh Daru Factory.

Category

Other

2

Description

Control group: Patients receive 1 milliliter of Normal Saline daily intravenously as Placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Marjan Lashgari

Street address

Sina Hospital., Hasan Abad Square., Emam Khomeini Ave

City

Tehran

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1136746911

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marjan0084@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Ali Sahrayian

Street address

In front of Central Organization., Inside of Central Pardis., Enghelab Ave., Enghelab Square

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141556619

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research@ut.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atabak Najafi

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Position

Fellowship of Critical care Medicine

Latest degree

Specialist

Other areas of specialty/work

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available