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 perfromed 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 mililiter daily as placebo.Patients consciousness daily via Four Score and Glascow Coma Score is evaluated and also Length of stay in ICU,mortality and time course to wakefullness 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 Malignanacy,

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 laoding dose of 40000 unit Erythropoietin intravenously and then after 8000 unit is injected daily until 2 weeks.In control group Normal Saline 1 mililiter is injected daily as placebo.

Main outcome variables
Level of Consciousness; Time course for wakefullness after first Erythropoietin or Placebo injection; Time course after Brain Injury unti first Erythropoietin or Placebo injection; Time course for increasing in Glascow Coma Score and Four Score after first Erythropoietin or Placebo injection; Incidense 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:

Oragn 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

Glascow Coma Score, Four Score

Secondary outcomes

1

Description

Time course for complete wakefullness after first Erythropoietin or Placebo injection

Timepoint

Daily until two weeks after Erythropoietin or Placebo injection

Method of measurement

Nursing Questionary

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 Glascow 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
Incidense 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 brian 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 uint (0/5 mililiter) which is prepared from Pooyesh Daru Factory.
Category
Other

2

Description
Control group:Patients receive 1 mililiter 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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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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Tehran
Province
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Postal code
141556619
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Email
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
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Person responsible for scientific inquiries

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Tehran University of Medical Sciences
Full name of responsible person
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Position
Full Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Marjan Lashgari
Position
Fellowship of Critical care Medicine
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Sina Hospital., Hasan Abad Square., Emam Khomeini Ave
City
Tehran
Province
Tehran
Postal code
1136746911
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+98 21 6634 8500
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