Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Clinical trial to compare the effect of erythropoietin and normal saline on level of consciousness of brain trauma patients admitted to intensive care unit

Protocol summary

Study aim

The aim of this study is to increase the level of Glasgow coma scale, determining mortality and comparing days needing verntilator, comparing admission duration and comparing Sequential Organ Failure Assessment (SOFA) in trauma patients admitted to the intensive care unit of Imam Hospital of Sari.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 68 patients. Study patients are divided into two groups by simple randomization method using random numbers table.

Settings and conduct

The present study will be performed in the intensive care unit of Imam Khomeini Hospital in Sari and 68 patients will be randomly divided into two groups: intervention (receiving erythropoietin) and control (receiving normal saline). This study is double-blind so that patients and the final evaluator will be unaware of how the intervention and control group is allocated.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes brain trauma with moderate GCS (7-12) during the first 24 hours after trauma with an expected time of at least 48 hours for the duration of hospitalization. Exclusion criteria is history of deep vein thrombosis pulmonary embolism, or any thromboembolic event; treatment with erythropoietin in the past 30 days; systolic blood pressure ≥160; history of heart failure and cancer; elective neurosurgery.

Intervention groups

The intervention group will receive 4000 units of subcutaneous erythropoietin made by Pooyesh Daroo Company with a volume of half a cc on days 1, 3 and 5 and the control group will receive half a cc of subcutaneous normal saline 0.9% on days 1, 3 and 5 . In both groups, patients are monitored for 14 days.

Main outcome variables

Level of consciousness; Deep vein thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181104041551N3**
Registration date: **2020-09-16, 1399/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-16, 1399/06/26**
Update count: **0**

Registration date

2020-09-16, 1399/06/26

Registrant information

Name

Fateme Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-21, 1399/05/31

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial to compare the effect of erythropoietin and normal saline on level of consciousness of brain trauma patients admitted to intensive care unit

Public title
Effect of erythropoietin on level of consciousness of brain trauma patients admitted to intensive care unit

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with brain trauma with moderate GCS (7-12) The first 24 hours after trauma Expected time for the duration of hospitalization, at least 48 hours

Exclusion criteria:
History of deep vein thrombosis, pulmonary embolism or any thromboembolic event Erythropoietin treatment in the last 30 days Systolic blood pressure ≥160 History of heart failure History of cancer Neurosurgery elective surgery

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to two groups of intervention and control with 34 members using block randomization with block sizes of 4. Randomization will be done using the software randomization option in Excel. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient and the final evaluator (intensive care subspecialist) will be unaware of the allocation in the study groups. Because the drug and placebo are colorless and there is no difference in subcutaneous injection. Because the project assistant is in the process of assigning groups, the intensive care unit sub-specialist is unaware of patients assignment to each group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee, Imam Hospital of Sari, Mazandaran University of Medical Sciences

Street address
Imam Hospital, Amir Mzandarani Blvd.

City
Sari

Province
Mazandaran

Postal code
5714854367

Approval date
2020-06-16, 1399/03/27

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1399.033

Health conditions studied

1

Description of health condition studied
Brain trauma patients admitted to the ICU

ICD-10 code
S06.3

ICD-10 code description
Focal traumatic brain injury

Primary outcomes

1

Description
Level of conciousness

Timepoint
Daily until 14 days

Method of measurement
Glasgow Coma Scale and SOFA four-point scale

2

Description
Deep vein thrombosis

Timepoint
Daily

Method of measurement
Daily visit of the limbs

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will receive 4000 units of subcutaneous erythropoietin made by Pooyesh Daroo Company with a volume of half a cc on days 1, 3 and 5
Category
Treatment - Drugs

2

Description
Control group: The control group will receive half a cc of subcutaneous normal saline 0.9% on days 1, 3 and 5 .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hospital of Sari
Full name of responsible person
Dr. Fatemeh Heydari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Majid Saeidi, Vice chancellor for research, Mazandaran University of Medical Sciences
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Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem square, Sari
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Heydari
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared
When the data will become available and for how long
Starting from April 2021
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Everyone
From where data/document is obtainable
Email to f.heydari@mazums.ac.ir
What processes are involved for a request to access data/document
Send email
Comments