

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 ventilator, 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

Email address

f.heydari@mazums.ac.ir

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 consciousness

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

Street address

Imam Hospital, Amir Mazandarani Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeidi, Vice chancellor for research,
Mazandaran University of Medical Sciences

Street address

Vice chancellor for research, Mazandaran University
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4817844718

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majsaeedi@yahoo.com

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 scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Farhad Mohammadnezhad

Position

Anesthesiology resident

Latest degree

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Other areas of specialty/work

Anesthesiology

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