

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### : Evaluation of the early effect of erythropoietin and testosterone in patients with neurological damage

#### Protocol summary

##### Study aim

Evaluation of the early effect of erythropoietin and testosterone in patients with neurological damage

##### Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 60 patients. In order to randomize, the block randomization method will be used.

##### Settings and conduct

Patients referred to Hazrat Rasool Hospital who have neurological damage caused by trauma will be enrolled in the study. Patients will be randomly divided into two groups based on blocks of 4. A total of 60 patients will be examined. Patients and the data analyst will be blinded.

##### Participants/Inclusion and exclusion criteria

Patients referred to Hazrat Rasool Hospital who have neurological damage caused by trauma will be enrolled in the study. Inclusion criteria: Patients over 12 years, Patients with neurological damage caused by brain trauma on radiograph or electroencephalogram with a GCS score of less than 9 Exclusion criteria: Patients over 60 years, Patients with fractures of other body parts, Patients with fractures of other organs and other problems requiring surgical intervention, such as internal bleeding, rupture of internal organs, severe chest trauma in the medical record or radiographic view, Patients with spinal cord trauma, Suffering from a dangerous trauma other than head trauma, including internal bleeding, systolic blood pressure drop less than 80 mmHg, and chest trauma within the first 24 hours.

##### Intervention groups

Intervention group: Patients will receive erythropoietin+testosterone (56,000 units subcutaneously) once a week for a maximum of three doses. Control group: Patients will receive placebo (0.9% sodium chloride subcutaneously) once weekly for a maximum of three doses.

##### Main outcome variables

level of consciousness; Deep venous thrombosis of the lower limb; Frequency of deaths

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170105031787N5**

Registration date: **2023-05-01, 1402/02/11**

Registration timing: **retrospective**

Last update: **2023-05-01, 1402/02/11**

Update count: **0**

##### Registration date

2023-05-01, 1402/02/11

##### Registrant information

##### Name

Mohammad-Reza Yasinzadeh

##### Name of organization / entity

Iran university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6652 5327

##### Email address

yasinzadeh.mr@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-10-23, 1401/08/01

##### Actual recruitment start date

2022-05-05, 1401/02/15

##### Actual recruitment end date

2022-11-21, 1401/08/30

##### Trial completion date

2022-11-21, 1401/08/30

**Scientific title**

: Evaluation of the early effect of erythropoietin and testosterone in patients with neurological damage

**Public title**

: Evaluation of the early effect of drugs in patients with neurological damage

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients over 12 years Patients with neurological damage caused by brain trauma on radiograph or electroencephalogram with a GCS score of less than 9

**Exclusion criteria:**

Patients over 60 years Patients with fractures of other body parts Patients with fractures of other organs and other problems requiring surgical intervention, such as internal bleeding, rupture of internal organs, severe chest trauma in the medical record or radiographic view. Patients with spinal cord trauma Suffering from a dangerous trauma other than head trauma, including internal bleeding, systolic blood pressure drop less than 80 mmHg, and chest trauma within the first 24 hours.

**Age**

From **12 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly divided into two groups. The randomization tool will be a random sequence generation software called SAS. In addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. Block randomization method will be used for randomization. Block randomization is for the purpose of making sure that exactly equal number of participants enter the study groups. The advantages of block randomization are that the balance of the number of participants in each group is guaranteed. For this purpose, 4 blocks will be formed and in each block, 2 people from intervention group and 2 people in control group will be placed. A total of 15 blocks will be considered to reach the sample size. The blocks contain numbers, odd numbers represent the intervention group and even numbers represent the control group. Their order will be determined by the software initially. Random allocation concealment will be done using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is

recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. the door At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will be blinded to the type of treatment. To hide similar and identical sera, it was used without drug name label and only with code. Patients will be aware that they will be randomly assigned to one of the two treatment groups, but will not know which treatment will be provided in that group. Patients will be assigned to one of two groups using a random number table. The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the data based on groups 1 and 2 and will not know the type of treatment provided in the groups and will be kept blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2021-02-23, 1399/12/05

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.662

**Health conditions studied****1****Description of health condition studied**

Neurological damage caused by brain trauma

**ICD-10 code**

G98.8

## ICD-10 code description

Other disorders of nervous system

## Primary outcomes

### 1

#### Description

level of consciousness

#### Timepoint

Before the intervention and 1 week after the intervention

#### Method of measurement

Glasgow coma criteria

### 2

#### Description

Deep venous thrombosis of the lower limb

#### Timepoint

After intervention

#### Method of measurement

Based on ultrasound

### 3

#### Description

Frequency of deaths

#### Timepoint

After intervention

#### Method of measurement

Based on the information in the patient's record

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients will receive erythropoietin+testosterone (56,000 units subcutaneously) once a week for a maximum of three doses. Patients will receive the first dose of erythropoietin + testosterone in the amount of 40,000 units intravenously within 10 minutes from the onset of symptoms, up to the first 24 hours. After that, the patient will receive 8,000 units of the drug every week. will receive up to 2 times. In fact, a total of 56,000 units of erythropoietin + testosterone will be prescribed for each patient. Intravenous injection of erythropoietin will be done without mixing with other drugs or intravenous fluids

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients will receive placebo (0.9% sodium chloride subcutaneously) once weekly for a maximum of three doses. In the control group, injection

will be done with distilled water. In the shortest possible time from the onset of symptoms, up to the first 24 hours, the first dose will be received intravenously within 10 minutes, after that, the patient will receive placebo up to 2 times a week.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul-Akram Hospital

##### Full name of responsible person

Vahid Ghorbani

##### Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

##### City

Tehran

##### Province

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##### Postal code

1445613131

##### Phone

+98 21 6435 2222

##### Email

Rasoolhospital@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hossein Keyvani

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##### Phone

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research@iums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Vahid Ghorbani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

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**Email**

vahid\_ghorbanikj91@yahoo.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Vahid Ghorbani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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

Iran University of Medical Sciences

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Resident

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**Email**

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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*