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

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Name of organization / entity
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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

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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
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Sponsors / Funding sources

1

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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
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
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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