Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of subcutaneous erythropoietin on blood transfusions requirement in trauma patients admitted to the surgical intensive care unit (SICU): A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of erythropoietin on the need for blood transfusion in trauma patients admitted to the surgical intensive care unit of Shahid Jalil Hospital, Yasuj.

Design
Controlled clinical trial, with parallel groups, single-blind, randomized, phase 3 on 140 patients. Block method for randomization

Settings and conduct
Trauma patients without the need for emergency laparotomy and with femoral fracture with or without other trauma, who have hemoglobin of 8 to 12 g/dL on the day of admission to the surgical ICU of Shahid Jalil Hospital, Yasuj, are eligible for entry into the study. Blocking method will be used to allocate individuals to the study groups Outcomes will be assessed by an independent assessor who is unaware of the subject's allocation (single-blind design). In this study, a dose of 30,000 units of recombinant human erythropoietin (rHuEPO) will be administered subcutaneously every three days (on days 3, 6, 9, and 12) for intervention group. Both intervention and control groups will receive the standard care protocol for trauma patients in the SICU.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Ages 18-65 years with trauma injuries with femur fracture admitted to SICU with hemoglobin level of 8 to 12 g/dL upon admission to ICU Exclusion criteria: pre-existing hematological disorders (such as polycythemia vera), history of erythropoietin sensitivity, current pregnancy or breastfeeding, chronic kidney disease requiring dialysis, history of erythropoietin or other red blood cell stimulating agents, history of hypertension, cancer patients, history of thrombosis or current acute thrombosis.

Intervention groups
Intervention group receiving erythropoietin and standard care and control group receiving standard care without erythropoietin

Main outcome variables
Number of blood transfusions required during SICU stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250621066213N1**
Registration date: **2025-07-01, 1404/04/10**
Registration timing: **prospective**

Last update: **2025-07-01, 1404/04/10**
Update count: **0**

Registration date
2025-07-01, 1404/04/10

Registrant information

Name
Saeid Sharifi Golshan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-11, 1404/04/20

Expected recruitment end date
2025-11-11, 1404/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of subcutaneous erythropoietin on blood transfusions requirement in trauma patients admitted to the surgical intensive care unit (SICU): A Randomized Clinical Trial

Public title

Investigating the effect of subcutaneous erythropoietin on blood transfusions requirement in trauma patients admitted to the surgical intensive care unit (SICU)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients 18-65 years old Patients admitted to the SICU with traumatic injuries associated with femur fractures Hemoglobin level 8 to 12 g/dL upon admission to the ICU Informed consent has been obtained from the patient or their legal representative.

Exclusion criteria:

Patients with pre-existing hematological disorders (such as polycythemia Vera) Patients with a history of erythropoietin sensitivity Pregnant or breastfeeding women Patients with chronic kidney disease who require dialysis Patients who have previously received erythropoietin or other red blood cell stimulating agents Patients with a history of high blood pressure Cancer patients Patients with a history of thrombosis or current acute thrombosis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The block method will be used. The groups are defined as codes A and B. Before assigning individuals to one of the groups, a list of these letters (blocks A, B) is formed. Each of the referring and eligible individuals is assigned to one of the groups. To avoid the risk of predicting the allocation of individuals to different groups, blocks of different sizes (2, 4, 6, and 8) will be created and, accordingly, they will be placed in two intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to reduce bias, the intervention will be implemented by trained therapists, and the outcome assessment will be conducted by an independent evaluator unaware of the subjects' grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences، Shahid Motahari Blvd، Yasuj، Postal code 7591741417

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

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Approval date

2025-05-25, 1404/03/04

Ethics committee reference number

IR.YUMS.REC.1404.038

Health conditions studied

1

Description of health condition studied

Investigating the need for blood transfusion in trauma patients receiving subcutaneous erythropoietin.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Number of blood transfusions required during SICU stay

Timepoint

During hospitalization in the intensive care unit

Method of measurement

Number of units of blood transfused

Secondary outcomes

1

Description

Hemoglobin level

Timepoint

When admitted to the ICU, weekly intervals, and discharged from the ICU...

Method of measurement

grams per deciliter

2

Description

Hematocrit level

Timepoint

When admitted to the ICU, weekly intervals, and discharged from the ICU...

Method of measurement

percentage

3

Description

Length of stay in the intensive care unit

Timepoint

When discharged from the ICU

Method of measurement

number of days

4

Description

Occurrence of thromboembolic complications

Timepoint

during ICU stay

Method of measurement

yes/no

Intervention groups

1

Description

Intervention group: Intervention group receiving erythropoietin and standard care .A dose of 30,000 units of recombinant human erythropoietin (rHuEPO) will be administered subcutaneously once every three days (on days 3, 6, 9, and 12)

Category

Treatment - Drugs

2

Description

Control group: control group receiving standard care without erythropoietin

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dowlatabad Martyrs' Educational and Medical Center and Shahid Dr. Ghorbanali Jalil Hospital

Full name of responsible person

Masoumeh Alizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Sirus Salehnasab

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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

Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Zeinab Alizadeh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In pdf format and via email after verification of the real requesting party
When the data will become available and for how long
No restrictions
To whom data/document is available
Real scientific characters
Under which criteria data/document could be used
To assist in the scientific study of statistics in order to advance science
From where data/document is obtainable
To personal email alizadeh.md6010@gmail.com
What processes are involved for a request to access data/document
After receiving the request via email with complete details of the workplace, address, and telephone number, after checking the verification of the real person and the accredited scientific center, a response will be

sent within one month.

Comments