

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Investigating the neuroprotective effect of erythropoietin in patients with severe traumatic brain injury

#### Protocol summary

##### Study aim

The role of neuroprototic erythropoietin in overcoming severe brain trauma

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 136 patients. It is used for block randomization with sealed envelopes

##### Settings and conduct

In Shahid Kamyab Hospital of Mashhad, with a sample size of 136 people who were randomly divided into two groups, and in the experimental group, erythropoietin was injected in the first six hours, and then repeated on the third, sixth, ninth, and twelfth days, subcutaneously, and in the control group, We inject normal saline subcutaneously in the first six hours on the third, sixth, and twelfth days, and the consequences are checked by GCS alertness assessment weekly during hospitalization and six months after discharge with GOS

##### Participants/Inclusion and exclusion criteria

All patients with severe brain trauma with glasgow scale score (GCS) are less than eight, less than six hours past their trauma and have between 18 and 75 years of age And they have no history of coagulation and DVT disorders and chronic kidney disorders

##### Intervention groups

The sample is divided into two groups after randomization, erythropoietin is injected subcutaneously in one group and normal saline is injected subcutaneously in the other group.

##### Main outcome variables

Glasgow coma scale (GCS), Glasgow outcome scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230901059316N1**

Registration date: **2024-01-16, 1402/10/26**

Registration timing: **prospective**

Last update: **2024-01-16, 1402/10/26**

Update count: **0**

##### Registration date

2024-01-16, 1402/10/26

##### Registrant information

###### Name

Afshin Eslamirad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3866 1788

###### Email address

eslamirada971@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-21, 1402/11/01

##### Expected recruitment end date

2024-10-10, 1403/07/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the neuroprotective effect of erythropoietin in patients with severe traumatic brain injury

##### Public title

Investigating the neuroprotective effect of erythropoietin in severe brain trauma

##### Purpose

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Patients with brain trauma with GCS consciousness less than eight who have been treated medically Less than six hours have passed since the patient's trauma

**Exclusion criteria:**  
Chronic coagulation disorders Chronic kidney disease History of DVT and pulmonary embolism

**Age**  
From **15 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **136**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The envelope method is that the envelopes will be prepared and printed and placed inside the envelope by a member of the research team and random numbers with the help of Randomaize.com. The envelope door will be closed and the contents will not be visible from the outside. The purpose of the study is then first explained to the person who has the conditions set forth, and the person, if desired, signs the informed consent form and removes an envelope and then opens it It enters into the intervention or control group based on the contents of the individual envelope.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The participant and the nurse do not know about the injection drug that is erythropoietin or placebo

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Mashhad University of Medical Sciences

**Street address**  
Faculty of Medicine, azadi square

**City**

Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177948564

**Approval date**  
2023-01-24, 1401/11/04

**Ethics committee reference number**  
IR.MUMS.MEDICAL.REC.1402.270

## Health conditions studied

1

**Description of health condition studied**  
Severe brain trauma

**ICD-10 code**  
**ICD-10 code description**

## Primary outcomes

1

**Description**  
The effect of erythropoietin on increased alertness is measured by periodic examinations based on a score from GCS (Glasgow coma scale)

**Timepoint**  
Six weeks and six months after the intervention

**Method of measurement**  
Glasgow coma scale ,Glasgow outcome scale

## Secondary outcomes

empty

## Intervention groups

1

**Description**  
Intervention group: 100 mg per kilogram of erythropoietin in six hours of arrival and then repeated in the third, sixth, ninth and twelfth days

**Category**  
Treatment - Drugs

2

**Description**  
Control group: Injection of 10 cc normalsalin 0/9 % in six hours upon arrival and then repeated on the third, sixth, ninth and twelfth days.

**Category**  
Placebo

## Recruitment centers

1

**Recruitment center**  
**Name of recruitment center**

Shahid kamyab hospital  
**Full name of responsible person**  
Afshin Eslamirad  
**Street address**  
Fadaeyan eslam st  
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eslamirada971@mums.ac.ir  
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<https://h-kamyab.mums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Mohsen tafghodi  
**Street address**  
Azadi square  
**City**  
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**Email**  
MDS.Dean@mums.ac.ir  
**Web page address**  
<https://www.mums.ac.ir/>

#### Grant name

**Grant code / Reference number**

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

Yes

#### Title of funding source

Mashhad 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**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Afshin eslamirad  
**Position**  
neurosurgery resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Neurosurgery  
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Fadaeian Islam St  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
Resident of neurosurgery  
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Medical doctor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Afshin eslamirad

**Position**

Resident of neurosurgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

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**Email**

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**Web page address**

<https://h-kamyab.mums.ac.ir>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available