

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### Evaluating the effects of combination therapy with Erythropoietin and Methylprednisolone in patients with traumatic cervical spinal cord injury

#### Protocol summary

##### Study aim

This study was aimed to investigate the effect of recombinant human erythropoietin (rhEPO) on functional outcome and disability in patients with traumatic cervical spinal cord injury (TCSCI).

##### Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence

##### Settings and conduct

Patients with acute traumatic cervical spinal cord injury admitted within 8 hours after injury were randomly assigned into two groups and either received only the standard regimen of methylprednisolone or rhEPO plus the standard regimen of methylprednisolone. All the patients underwent the surgery within the next several days. Neurological function was assessed on admission, and at 6th and 12th months after the injury. The patients and the people responsible for data collection and analysis were blinded. The assignment of patients was concealed using sealed envelopes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with traumatic cervical spinal cord injury were included. Exclusion criteria: patients with current or past history of cardiovascular, neurological, psychiatric and renal disease, pregnant and lactating women, and those with allergy to erythropoietin or human albumin were excluded.

##### Intervention groups

The control group received only the standard regimen of methylprednisolone and the intervention group received rhEPO 500IU/mL plus the standard regimen of methylprednisolone.

##### Main outcome variables

American Spinal Injury Association (ASIA) score, mortality, Sphincter function after 6 and 12 months

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180923041103N1**

Registration date: **2020-02-09, 1398/11/20**

Registration timing: **retrospective**

Last update: **2020-02-09, 1398/11/20**

Update count: **0**

##### Registration date

2020-02-09, 1398/11/20

##### Registrant information

##### Name

Mohammad Ali abouei mehrizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3727 9451

##### Email address

drabouei@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2015-12-19, 1394/09/28

##### Expected recruitment end date

2016-03-18, 1394/12/28

##### Actual recruitment start date

2015-12-19, 1394/09/28

##### Actual recruitment end date

2016-03-18, 1394/12/28

##### Trial completion date

2017-04-19, 1396/01/30

##### Scientific title

Evaluating the effects of combination therapy with Erythropoietin and Methylprednisolone in patients with traumatic cervical spinal cord injury

#### Public title

The effect of erythropoietin on acute spinal cord injury

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patient with Acute Traumatic Cervical Spinal Cord Injury  
Admitted within 8 hours of injury  
Neurological lesion at C5 to C7 level  
Stable hemodynamics

##### Exclusion criteria:

Vascular Brain Disease  
Acute Myocardial Infarction  
Thrombotic Diseases  
Cardiac Arrhythmia  
Heart Failure  
Peripheral Vascular Disorders  
Polycythemia  
Porphyria  
Malignancy  
Neurological Disorders  
Known Psychiatric Disorders  
Acute or Chronic Kidney Disease  
Acute Spinal Cord Injury caused by weapons  
Pregnancy  
Lactation  
Allergy to Erythropoietin or Human Albumin

#### Age

No age limit

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **54**

Actual sample size reached: **54**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, all eligible patients were assigned to control and intervention groups using random sequence extraction from the computer (via [www.randomization.com](http://www.randomization.com)) and simple randomization. The resulting random numbers, i.e. the allocation of patients to groups, was concealed using sealed envelopes.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The patients and the people responsible for data collection and analysis were blinded. The assignment of patients was concealed using sealed envelopes.

#### Placebo

Not 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

Daneshgah St., central building of Mashhad University of Medical Sciences

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Approval date

2015-12-19, 1394/09/28

##### Ethics committee reference number

IR.MUMS.REC.1394.574

## Health conditions studied

### 1

#### Description of health condition studied

Traumatic Cervical Spinal Cord Injury

#### ICD-10 code

S14

#### ICD-10 code description

Injury of nerves and spinal cord at neck level

## Primary outcomes

### 1

#### Description

American Spinal Injury Association (ASIA) score

#### Timepoint

Baseline, 6 and 12 months after intervention

#### Method of measurement

Medical History and Physical Examination

### 2

#### Description

Sphincter Function

#### Timepoint

Baseline, 6 and 12 months after intervention

#### Method of measurement

Physical Examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: methyl prednisolone (500 mg lyophilized vials, Ronak Daroo, Iran), 30 mg/kg IV infusion for the first hour followed by 5.4 mg/kg/h in the next 23 hours if referred within 3 hours of injury; or if referred to the ED between the third and eighth hour after the trauma underwent treatment based on National Acute Spinal Cord Injury Study (NASCIS) III protocol for the following 47 hours.

#### Category

Treatment - Drugs

## 2

#### Description

Intervention group: underwent treatment with both methyl prednisolone (500 mg lyophilized vials, Ronak Daroo, Iran), based on the NASCIS III protocol and erythropoietin (10000 U ampules, CinnaGen, Iran), 500 IU/kg in 50 ml of saline solution being infused over 30 minutes and the treatment continued in the next 24 hours.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Shahid Kamyab Hospital, Mashhad University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Abouei Mehrizi

##### Street address

Shahid Kamyab Hospital, Fadaeyan Eslam St.

##### City

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##### Province

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##### Postal code

9166637477

##### Phone

+98 51 3859 2121

##### Email

skh.pr@mums.ac.ir

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Central building of Mashhad University of Medical Sciences, Daneshgah 16, Daneshgah St.

##### City

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##### Province

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##### Postal code

1394491388

##### Phone

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##### Email

presidentoffice@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

Gholamreza Bahadoorkhan

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurosurgery

##### Street address

Ghaem hospital, Ahmad Abad Blvd.

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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Associate professor

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Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
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Mashhad University of Medical Sciences  
**Full name of responsible person**  
Mohammad Ali Abouei Mehrizi  
**Position**  
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9166637477  
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+98 51 3859 2121  
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drabouei@yahoo.com

## 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