

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)

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+98 51 3727 9451

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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) 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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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