

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the efficacy of erythropoietin and methyl prednisolone in improving muscle strength or sensory level outcomes in patients with spinal cord injury.

Protocol summary

Summary

The aim of the study: to evaluate the improvement of sensory and muscle strength in patients with spinal cord injury and enzyme changes, malondialdehyde, and total antioxidant capacity in the two groups., Double-blind study conducted in 60 patients with traumatic spinal cord injury complications decreased muscle strength or sensory level according to Frankel classification A - E and during first 24 hours of trauma have been admitted in Emamreza hospital. admission status, sensory, motor, according to Frankel classification has been is performed, blood samples To check the amount of enzyme, malondialdehyde and total antioxidant capacity will be taken . The bullous form of methylprednisolone 33mg/kg intravenous infusion within fifteen minutes and after 45 minute, 5.4mg/kg methylprednisolone infusion within 23-47 hours, will continue. Patients were divided into two groups, the first group of methylprednisolone, after obtaining the consent of the patient, erythropoietin, or 500 units per kilogram of body weight as an intravenous infusion over 3 divided doses in three days will be in the second group further treatment will not be added. , In both groups, the rate of enzyme levels, muscle strength, and sensory level at the fourth and eighth days will be check. Inclusion criteria: patients with spinal cord injury and loss of muscle strength and sensory . Exclusion criteria: patients with hypertension poor control ,history of thromboembolic events, patients with brain damage due to a lower GCS determination of the patient's sensory and motor. Variables assessed: Evaluation of malondialdehyde and antioxidant enzyme levels and muscle weakness and sensory level is classified as Frankel .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041417272N1**

Registration date: **2014-07-04, 1393/04/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-04, 1393/04/13

Registrant information

Name

Nasrin Pourhajshokr

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences, Center for Neuroscience Research

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of erythropoietin and methyl prednisolone in improving muscle strength or sensory level outcomes in patients with spinal cord injury.

Public title

Efficacy of Intravenous erythropoietin in patients with spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who develop symptoms of spinal cord injury and decrease muscle strength or sensory level deficit Frankel classification A - E Exclusion criteria: Patients with uncontrolled hypertension, patients allergic to human albumin, Pregnancy and lactation, erythroid leukemia, Patients with a history of thromboembolic events. in patients with severe coronary artery disease , peripheral arteries, the carotid"brain,brain-damaged patients with low GCS due to lack of accurate sensory, motor cases

Age

From **1 year** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Science

Street address

2 Central Building, Deputy of Research and Technology, Tabriz University of Medical Science, Golgasht street, Tabriz

City

Tabriz

Postal code

Approval date

2013-06-17, 1392/03/27

Ethics committee reference number

3844/4/5

Health conditions studied

1

Description of health condition studied

Spinal cord injury

ICD-10 code

G90-G99

ICD-10 code description

G95.2 کمپرشن کانال نخاعی

Primary outcomes

1

Description

The muscle strength scoring Franklin A-E

Timepoint

Admission, fourth day of admission, the eighth day of admission

Method of measurement

Examination by resident Brain surgery

2

Description

The sensory strength scoring Franklin A-E

Timepoint

Admission, fourth day of admission, the eighth day of admission

Method of measurement

Examination by resident Brain surgery

Secondary outcomes

1

Description

The level of enzyme levels, total Antioxidant capacity

Timepoint

Admission, Fourth day of admission, Eight day of admission

Method of measurement

Kerry measured by enzymatic kits for lab

2

Description

The level of enzyme levels, Malon dy Aldehyd

Timepoint

Admission, Fourth day of admission, Eight day of admission

Method of measurement

Kerry measured by enzymatic kits for lab

Intervention groups

1

Description

Methylprednisolone 33mg/kg were referred to as bullous within fifteen minutes then 5.4mg/kg methylprednisolone infusion within 23-47 hours.

Category

Treatment - Drugs

2

Description

Intervention group. First Methylprednisolone 33mg/kg were referred to as bullous within fifteen minutes then 5.4mg/kg methylprednisolone infusion within 23-47 hours. then Erythropoietin 500 units per kg of body weight as an intravenous infusion over 3 days will be given in 3 divided doses

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Tabriz

Full name of responsible person

Dr nasrin pourhajshokr

Street address

Imam Reza Hospital, Golgasht street, Tabriz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences, MediCenter for Neuroscience Research

Full name of responsible person

Dr Ali Meshkini

Street address

2 Central Building, Deputy of Research and Technology, Imam Reza Hospital, Tabriz University of Medical Sciences

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences, MediCenter for Neuroscience Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Nasrin Pourhajshokr

Position

Surgical Residency in Neurology

Other areas of specialty/work

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Other areas of specialty/work

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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