Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Effects of Human Recombinant Erythropoietine on Functional Outcome of Traumatic Cervical Spine Cord Injury; A Randomized Placebo Controlled Study

Protocol summary

Summary

The aim of the present study is to determine the effects of high dose recombinant erythropoietin (EPO) during eight hours after traumatic cervical spinal cord injury on functional outcome. A total of 20 patients with acute traumatic cervical spinal cord injury less than 8 hours after injury were included. We excluded those with anatomic cord dissection, penetrating cord injury and significant concomitant injury. Patients will randomly assigned to receive recombinant EPO in 500IU/mL dosage immediately and 24-hour later (n=10) or placebo (n=10). To assess improvement from baseline, neurological function will be assessed and scored at month 1, 6 and 12 using the American Spinal Cord Injury Association (ASIA) standardized neurological examination, including the motor and sensory composites.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122920471N1**
Registration date: **2015-04-26, 1394/02/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-26, 1394/02/06

Registrant information

Name

Mohammad Hossein Ashraf

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3627 4259

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Human Recombinant Erythropoietine on Functional Outcome of Traumatic Cervical Spine Cord Injury; A Randomized Placebo Controlled Study

Public title

Effects of human erythropoietine in improvement of traumatic cervical cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Acute cervical cord injury Less than 8 hours from injury. Exclusion criteria: Anatomic cord dissection; Penetrating cord injury; Injury beyond cervical cord; Significant concomitant injury; Contraindication for methylprednisolone; Contraindication for erythropoietin; Patient refuses the study

Age

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical science

Street address
Zand Ave

City
Shiraz

Postal code

Approval date
2013-08-04, 1392/05/13

Ethics committee reference number
CT-92-4315

Health conditions studied

1

Description of health condition studied
Traumatic Cervical Cord Injury

ICD-10 code
S14

ICD-10 code description
Injury of nerves and spinal cord at neck level

Primary outcomes

1

Description
Neurological examination

Timepoint
Before, 1,3,6 months after intervention

Method of measurement
examining by physician

Secondary outcomes

empty

Intervention groups

1

Description
recombinant erythropoietin, intravenous, 500 IU, stat and repeat that after 24 hour

Category
Treatment - Drugs

2

Description
equal volume of normal saline, intravenous, stat and 24 hour later

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaee Hospital

Full name of responsible person
Mohammad Hossein Ashraf

Street address
Shahid Rajaei Hospital, Chamran Avenue

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Science

Full name of responsible person
Vice Chancellor of Research

Street address
7th Floor, Shiraz University of Medical Sciences, Zand Blvd

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz University of Medical Science

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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