Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of intravenous ceftriaxone in neurologic outcome of acute spinalcord injury patients compared with methylprednixolone alone

Protocol summary

Summary

Aim: Investigation of Effects of intravenous ceftriaxone in neurologic outcome of acute spinalcord injury patients compared with methylprednixolone alone Study design: Randomized Two-blinded clinical trial study Object Study: Patients with spinal cord injury refereed to Imam Reza hospital of Tabriz University of medical Sciences less than 8 hours after accident Inclusion criteria:Patients with spinal cord injury from T10 to L2; Patients with age of 17 to 60 ; Frankle grade A to D Exclusion criteria: Patients older or younger than 17-60; Patients with head trauma and GCS score lower than 13; Reaction to Ceftriaxone use; Amp Calcium intake or other drugs with calcium ; First trimester; E grade based on Frankel classification at admission; Spinal cord injury out of T10 to L2 Trials: After informed consent were obtained; all patients divided in two group randomly and frankel grading and Check of ESR and CRP obtained at admission. All patients will receive bolus infusion of methylprednisolon 33 mg/kg in 15 minutes intravenous and after 45 minutes they will receive 4,5 mg/kg infusion of methylprednisolon for 23-42 hours. Case group will receive 2 g ceftriaxon intra venous each 12 hours for 1 week. ESR, CRP and frankle grade in 1,4,7 6 months follow upwill be taken days after admission and data will analysed to campare between two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102713947N5**
Registration date: **2017-02-11, 1395/11/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-11, 1395/11/23

Registrant information

Name
Atta Mahdkhah

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 1332 6196

Email address
mshimia@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source
Road traffic injury prevention research center, Tabriz University of Medical Sciences

Expected recruitment start date
2016-12-21, 1395/10/01

Expected recruitment end date
2017-06-21, 1396/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of intravenous ceftriaxone in neurologic outcome of acute spinalcord injury patients compared with methylprednixolone alone

Public title
Effects of intravenous ceftriaxone in neurologic outcome of acute spinalcord injury patients compared with methylprednixolone alone

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Patients with spinal cord injury from T10 to L2; Patients with age of 17 to 60 ; Frankle grade A to D Exclusion criteria: Patients older or younger than 17-60; Patients with head trauma and GCS score lower than 13; Reaction to Ceftriaxone use; Amp Calcium intake or other drugs with calcium ; First trimester; E grade based on Frankel classification at admission; Spinal cord injury out of T10 to L2

Age

From **17 years** old to **60 years** old

Gender

Both

Phase

2-3

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

Deputy of Technology and Research,Tabriz University of Medical Sciences

Street address

Tabriz

City

Tabriz

Postal code

Approval date

2016-07-03, 1395/04/13

Ethics committee reference number

IR.TBZMED. REC.1395.434

Health conditions studied

1

Description of health condition studied

Spinal Injury

ICD-10 code

Ŝ34.1

ICD-10 code description

Other injury of lumbar spinal cord

Primary outcomes

1

Description

Investigation of Neurological status based on Frankel Grade

Timepoint

At admission and 6 month period after admission

Method of measurement

Based on Frankel grade

Secondary outcomes

empty

Intervention groups

1

Description

Case group will receivebolus infusion of methylprednisolon 33 mg/kg in 15 minutes intravenous and after 45 minutes they will receive 4,5 mg/kg infusion of methylprednisolon for 23-42 hours and 2 g ceftriaxon intra venous each 12 hours for 1 week

Category

Treatment - Drugs

2

Description

control group will receive bolus infusion of methylprednisolon 33 mg/kg in 15 minutes intravenous and after 45 minutes they will receive 4,5 mg/kg infusion of methylprednisolon for 23-42 hours.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Road traffic injury prevention research center, Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Road traffic injury prevention research center, Tabriz University of Medical Sciences

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

Department of Neurosurgery, Tabriz University of Medical Sciences

Full name of responsible person

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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