

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparing the efficacy of the intrathecal with intravenous Methylprednisolone administration in outcome of patients with acute thoracolumbar spinal cord injury (SCI)

Protocol summary

Study aim

determination of the efficacy of the intrathecal with intravenous methyl prednisolone administration in outcome of patients with acute thoracolumbar spinal cord injury (SCI)

Design

60 patients with acute spinal cord injuries will be selected for inclusion in the study, in accordance with the criteria for entry and exit. Patients will be divided into two groups in the first 8 hours of referral, so that 30 patients will be in the group receiving intraluminal methylprednisolone and 30 in the intravenous methylprednisolone group. To randomly select patients for study groups, a box will be designed. The patients will then be fully examined for signs and symptoms of the disease and for neurological performance in the sensory and motorway. . After performing the first steps and patient segmentation, patients in the first group will receive intravenous prednisolone and the second in the spinal cord.

Settings and conduct

Tabriz Imam Reza Hospital

Participants/Inclusion and exclusion criteria

□ Entry criteria: - Patients with acute spinal cord injury in the thoracolumbar region (Frankel A B C D degree) - Patients referred in the first 8 hours after injury □ Exit criteria: - Patients with nerve spinal cord injury or single injury Cauda equina - Damage following bullet injury - life-threatening injuries - Pregnant patients - Drug addicts or narcotics - Patients taking steroids for other reasons - Patients under 13 years of age - Contraindications for LP and any traumatic brain injury

Intervention groups

In this study, patients in the first 8 hours of referral will be randomized into two groups of study, so that 30 patients will be in the group receiving intraluminal methylprednisolone and 30 subjects will be treated with

intravenous methylprednisolone .

Main outcome variables

Sensory signs Symptoms of gastrointestinal tract infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190116042374N1**

Registration date: **2019-02-04, 1397/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-04, 1397/11/15**

Update count: **0**

Registration date

2019-02-04, 1397/11/15

Registrant information

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Morteza Khalilzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the efficacy of the intrathecal with intravenous Methylprednisolone administration in outcome of patients with acute thoracolumbar spinal cord injury (SCI)

Public title
Effect of Methylprednisolone in acute spinal cord injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All traumatic patients with acute thoracolumbar spinal cord injury Age over 13 years
Exclusion criteria:
Patients with nerve spinal cord injury or single injury Cauda equina Damage after injury with bullets Pregnant patients Patients receiving steroids for other reasons Patients under 13 years of age Patients with a history of receiving 100 mg of Methylprednisolone or a diet equal to it Diabetic patients Patients with immunodeficiency Patients Needing Emergency Surgery Loss of consciousness LP contraindications and any traumatic lesions of the brain

Age
From **13 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize the selection of patients for study groups, a box will be designed that will include 60 envelopes in the box, 30 of which are interattakal treatment, and 30 of which are intravenous treatment, which, after Referring to the patient, the resident examiner, he will randomly remove one of the papers from the box and place the patient in the group written on the paper.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients will be randomly assigned to one of the intrathecal or intravenous groups without knowing how to assign the intervention method. The researcher will use the method of randomization using the random sampling method to remove the envelope and will be

unaware of how the intervention method is allocated. An analyst will be unaware of how the intervention was performed, and based on this study, the three-blind study will be analyzed and analyzed after the analysis of the results based on the randomized map.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht Street.,Azadi Ave.,Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-01-14, 1396/10/24

Ethics committee reference number

IR.TBZMED.REC.1396.971

Health conditions studied

1

Description of health condition studied

A 48-hour regimen with methyl prednisolone in patients with acute spinal cord injuries significantly improves neurological symptoms in patients.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The evaluation of peroxidation metabolites (TAC) total antioxidant capacity (MDA) and malondialdehyde (MDA), which indicates the inflammatory status of the spinal cord, as well as sensory and motor status assessment based on ASIA and FRANKL grading at discharge

Timepoint

Patients will undergo a re-examination and assessment of sensory and motor status in three intervals at the time of discharge (day 7-10) of the sixth week (day 42-49)

and the sixth month (day 180-150)after treatment. On day 1 and 4 of admission, total antioxidant capacity and malondialdehyd (TAC and MDA)is measured.

Method of measurement

The sensory and motor status of the patient is measured at each turn with the examination and total antioxidant capacity and malondialdehyd metabolites in the laboratory by the device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Traumatic patients with acute spinal cord injuries injected intrathecal Methylprednisolone acetate with a dose of 1 mg per kg and this treatment protocol will be repeated 24 and 48 hours later.

Category

Treatment - Drugs

2

Description

Control group: Acute spinal injury trauma patients receiving intravenous Methylprednisolone acetate will receive a dose of intravenous bolus Methylprednisolone at a dose of 30 mg per kg body weight over a period of 15 minutes. Then, after a 45-minute delay, the dose The intravenous dose of 5.4 mg / body weight will be continued for 47 hours at the start of the first bolus dose for the first 3 hours, for 23 hours and starting at 3-8 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Ali Meshkini

Street address

Golgasht street, Azadi Ave, Emam Reza hospital

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Position

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