

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of minocycline on the neurological outcome of spinal cord injury patients

Protocol summary

Study aim

The effect of minocycline on neurological outcome of spinal cord injury patients

Design

The study is a randomized, community-based, and pragmatic clinical trial consisting of 60 patients in 2 parallel groups with a double-blind design

Settings and conduct

This study will be carried out at Tabriz Imam Hospital in a three-blind manner, only the head nurse will be aware of it, and the researcher and the patient and Analyzer will be unaware of it.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Patients with spinal cord injury from T10 to L2 .Patients with the age of 17 to 60, level of damage, neurologic exam according to the Frankel Grading System A to D.Exclusion criteria include: Patients older or younger than 17-60; Patients with head trauma and GCS score lower than 13, Reaction to Minocycline use

Intervention groups

Intervention group: will receive bolus infusion of methylprednisolone 33 mg/kg in 15 minutes intravenous and after 45 minutes they will receive 4,5 mg/kg infusion of methylprednisolone for 23-42 hours and 50mg minocycline orally every 12 hours for 1 week. Control group: placebo. will receive a bolus infusion of methylprednisolone 33 mg/kg in 15 minutes intravenous and after 45 minutes they will receive a 4,5 mg/kg infusion of methylprednisolone for 23-42 hours

Main outcome variables

Investigation of Neurological status based on Frankel Grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N15**

Registration date: **2022-09-10, 1401/06/19**

Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**

Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of minocycline on the neurological outcome of spinal cord injury patients

Public title

minocycline on the neurological outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with spinal cord injury from T10 to L2 Patients with age of 18 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 Minocycline use Spinal cord injury out of T10 to L2 Trials

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Random method: Block, Random unit: individual, Random Tool: Random Block 4. for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, and BAAB. For selecting each block, dice dropped and the block number will be selected. this procedure continued to complete the allocation and reached to sample size.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a double-blinded study and Researchers and patients are kept unaware of the intervention in each group In order to allocate concealment, the type of intervention will be written on paper and placed in numbered, matte, and packed envelopes. The envelopes will be opened in the order of participation of the participants and the type of group will be determined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz Medical School

Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2019-11-25, 1398/09/04

Ethics committee reference number

IR.TBZMED.REC.1398.881

Health conditions studied

1

Description of health condition studied

Spinal Injury

ICD-10 code

S34.1

ICD-10 code description

Other and unspecified injury of lumbar and sacral 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

Intervention group: will receive bolus infusion of methylprednisolone 33 mg/kg in 15 minutes intravenous and after 45 minutes they will receive 4,5 mg/kg infusion of methylprednisolone for 23-42 hours and 50mg minocycline orally every 12 hours for 1 week

Category

Treatment - Surgery

2

Description

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

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neurosurgery Ward of Imem Reza hospital

Full name of responsible person

Dr. Ali Meshkini

Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

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

Dr.Farhad Mirzaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

A portion of the data that represents the final outcome

When the data will become available and for how long

Access will be 6 months after the results are printed.

To whom data/document is available

Neuropsychiatric specialists in coordination with the presenter

Under which criteria data/document could be used

The use of data to improve patients' treatment processes is safe

From where data/document is obtainable

The person responsible for updating study information

What processes are involved for a request to access data/document

Requesting data and study documents will be done by correspondence with the person responsible for updating the study information

Comments