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)

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+98 41 3334 0830

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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 drooped 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 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
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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5166614756
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Meshkini
Street address
Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz
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Meshkinia@gmail.com
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 updating data

Contact

Name of organization / entity
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Full name of responsible person
Nima Allahyari sani

Position
Resident of Neurosurgery

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

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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