Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of riluzole on motor and sensory function of patients with post-traumatic acute spinal cord injury

Protocol summary

Summary

The objectives of this study is to evaluation the effect of riluzole on motor and sensory function of patients with post- traumatic acute spinal cord injury. Inclusion criteria are: 1. acute spinal cord injury with Frankel Impairment Scale level A to C 2. 18 to 70 years old 3. Informed consent 4. C4 to L2 vertebral fractures. Exclusion criteria are: 1. Hepatic or renal disorders 2. Penetrating brain trauma 3. Traumatic brain injury 4. Pregnancy or Breastfeeding 5. Recent alcohol consumption 6. Neurological or psychiatric disorders 7. Life threatening injuries 8. Unable to receive riluzole orally. 60 patients with acute spinal cord injury and Frankel Impairment Scale level A, B or C will be selected and matched based on age, sex and Frankel Impairment Scale level in two equal groups of A and B. Rilozul therapy will be performed in group A and after 6 months, sensory and motor examinations will be done in all of patients. This study will be done in a randomized, double bind, with use of placebo, in one center and trial phase of 2. Evaluation will be done in three post-interventional phases: early, after 6 weeks and after 6 months with 50mg PO (by mouth) every 12 hours continuing for 4 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031813947N3**
Registration date: **2014-07-16, 1393/04/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-16, 1393/04/25

Registrant information

Name
Atta Mahdkhah
Name of organization / entity
Tabriz University of Medical Sciences
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mshimia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of riluzole on motor and sensory function of patients with post- traumatic acute spinal cord injury

Public title

The effect of riluzole on spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. acute spinal cord injury with Frankel Impairment Scale level A to C; 2. 18 to 70 years old; 3. Informed consent; 4. C4 to L2 vertebral fractures
Exclusion criteria: 1. Hepatic or renal disorders; 2. Penetrating brain trauma; 3. Traumatic brain injury; 4. Pregnancy or Breastfeeding; 5. Recent alcohol

consumption; 6. Neurological or psychiatric disorders; 7. Life threatening injuries; 8. Unable to receive riluzole orally

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

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
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
Ethics committee of Tabriz University of Medical Sciences, Golgash St, Tabriz, Iran

City
Tabriz

Postal code
5165687386

Approval date
2014-01-21, 1392/11/01

Ethics committee reference number
92219

Health conditions studied

1

Description of health condition studied
Spinal injury

ICD-10 code
S34.1

ICD-10 code description
Injury of nerves and lumbar spinal cord at abdomen, lower back and pelvis level

Primary outcomes

1

Description
Sensory injury

Timepoint
Primary, 6 weeks and 6 months following end of treatment

Method of measurement
Frankel classification

2

Description
Motor injury

Timepoint
Primary, 6 weeks and 6 months following end of treatment

Method of measurement
Frankel classification

3

Description
Pain

Timepoint
Primary, 6 weeks and 6 months following end of treatment

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Side effects

Timepoint
Primary, 6 weeks and 6 months following end of treatment

Method of measurement
Physical examination

Intervention groups

1

Description
Rilozul therapy will be performed in group A and after 6 months, sensory, motor and pain examinations will be done in all of patients. Rilozul will be administrated 50mg PO (by mouth) every 12 hours continuing for 4 weeks.

Category
Treatment - Drugs

2

Description
Placebo will be administrated to control group and after 6 months, sensory and motor examinations will be done.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital,Tabriz University of Medical Sciences,

Full name of responsible person
Atta Mahdkhah

Street address
Golgasht St, Azadi Ave, Tabriz, Iran

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person
Ali Meshkini

Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht St, Azadi Ave, Tabriz, Iran

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for research of 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Atta Mahdkhah

Position
Neurosurgery Resident

Other areas of specialty/work

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Tabriz University of Medical Sciences, Golgash St, Azadi Ave, Tabriz, Iran

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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