Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of Riluzole efficacy on cognitive and functional outcome of severe traumatic brain injury patients

Protocol summary

Study aim
Evaluation of Riluzole efficacy on cognitive and functional outcome of severe traumatic brain injury patients

Design
This study is a double-blind trial with parallel groups in which 50 patients with traumatic brain injury are divided into two identical intervention and control groups using block randomization method.

Settings and conduct
This study is a two-blind trial in which 50 patients with severe traumatic brain injury referred to Vali Asr Hospital in Arak are admitted to the study. These people are divided into two equal groups of intervention and control using the block randomization method. In the intervention group, riluzole was administered for 2 weeks at a dose of 500 mg every 12 hours, preferably during the first 12 hours after trauma and at the first opportunity after the ability to eat by mouth. In the control group, distilled water is used instead of riluzole. Finally, The two groups are compared in terms of main outcomes.

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients with severe traumatic brain injury, Impenetrable brain injury, Age over 16 years, Ability to receive medication through the mouth or nasogastric tube, Glasgow Coma Scale less than 9, Having informed consent by family members primarily to participate in the study Non-entry criteria: Kidney and liver failure, History of severe brain injury, Unidentifiable patients and Pregnancy .

Intervention groups
Intervention group: The treatment protocol included administration of the drug (riluzole) for 2 weeks, at a dose of 500 mg every 12 hours, preferably during the first 12 hours after trauma and at the first opportunity after the ability to eat by mouth. Control group: Distilled water will be prescribed instead of riluzole

Main outcome variables
Glasgow Coma Scale, 4 scores, Karnovsky performance status, Glasgow outcome scale, Mini Mental State Test, Disability Rating Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191104045328N6**
Registration date: **2021-04-30, 1400/02/10**
Registration timing: **prospective**

Last update: **2021-04-30, 1400/02/10**
Update count: **0**

Registration date
2021-04-30, 1400/02/10

Registrant information

Name
Amin Haji seyyed hoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3366 7583

Email address
amin.medstu@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2022-03-06, 1400/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Riluzole efficacy on cognitive and functional outcome of severe traumatic brain injury patients

Public title
Evaluation of the effect of riluzole in improving the condition of patients with severe traumatic brain injury

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with severe traumatic brain injury Impenetrable brain injury Age over 16 years Ability to receive medication through the mouth or nasogastric tube Glasgow Coma Scale (GCS) less than 9 Having informed consent by family members primarily to participate in the study

Exclusion criteria:
Kidney and liver failure History of severe brain injury (tumor or stroke) Unidentifiable patients Pregnancy

Age
From **16 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are assigned to two intervention and control groups, respectively, based on the randomization sequence that will be generated beforehand. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate samples. Thus, using block numerical random number generation software, a randomization sequence proportional to the sample size required for the two groups will be generated. Initially, all cases in which the two letters A and B can be arranged in blocks of 8 are produced. A block is then randomly selected from the blocks and the layout pattern in that block will be used to assign participants. This block will then be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the process of blinding, the treating physician and the patient are blind and the trained assistant is in the process of studying. The person completing the questionnaire is the same trained assistant or facilitator.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2020-09-06, 1399/06/16

Ethics committee reference number
IR.ARAKMU.REC.1399.191

Health conditions studied

1

Description of health condition studied
Traumatic brain injury

ICD-10 code
S06.2

ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Glasgow Coma Scale

Timepoint
Upon arrival of the patient, after initial resuscitation, third day, seventh day

Method of measurement
Glasgow Coma Scale Checklist

2

Description
4 score

Timepoint
Upon arrival of the patient, after initial resuscitation, third day, seventh day day
Method of measurement
4 score checklist

3

Description
glasgow outcome scale
Timepoint
First month after intervention, Sixth month after intervention
Method of measurement
glasgow outcome scale checklist

4

Description
Karnovsky performance status
Timepoint
First month after intervention, Sixth month after intervention
Method of measurement
Karnovsky performance status checklist

5

Description
Mini Mental State Test
Timepoint
First month after intervention, Sixth month after intervention
Method of measurement
Mini Mental State Test

6

Description
Disability Rating Scale
Timepoint
First month after intervention, Sixth month after intervention
Method of measurement
Disability Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The treatment protocol includes administration of the drug (riluzole) for 2 weeks, at a dose of 500 mg every 12 hours, preferably during the first 12 hours after trauma and at the first opportunity after the ability to eat by mouth.
Category
Treatment - Drugs

2

Description
Control group: Distilled water is administered for 2 weeks every 12 hours, preferably during the first 12 hours after trauma and at the first opportunity after the ability to eat by mouth.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr hospital
Full name of responsible person
Dr Aidin Shakeri
Street address
Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran
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3814957558
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak 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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr Mohsen Dalvandi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for scientific inquiries

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Full name of responsible person
Dr Aidin Shakeri

Position
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Other areas of specialty/work
Neurosurgery

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Person responsible for updating data

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Dr Hadi Rezvani

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2022/4/20 to 2026/4/20 for 4 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

If there are any further questions

From where data/document is obtainable

Dr Aidin Shakeri

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

Letter writing should be done with professors and universities.

Comments