# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Dr Alireza Kmali
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Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
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**Email**
alikamaliir@yahoo.com
**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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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

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**Full name of responsible person**
Dr Hadi Rezvani

**Position**
Rezident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Neurosurgery

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rezvani.hadi59@gmail.com

## 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**