

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the effectiveness of amitriptyline in preventing headache and sleep disorders in patients with mild brainstorming

#### Protocol summary

##### Study aim

Prevention of headache and sleep disorders in patients with traumatic brain injury

##### Design

This study is a double-blind randomized clinical trial with a control group and parallel groups. Phase 2 was performed on 110 patients and rand function of Excel software was used for randomization.

##### Settings and conduct

This study is a double-blind randomized clinical trial with patient and researcher blinding, which will be conducted at Al-Zahra Medical Center, Isfahan University of Medical Sciences. The studied population will be patients with mild brain trauma who will be treated with medication to reduce headache and insomnia disorders. In the intervention group, amitriptyline was started with a dose of 10 mg and continued up to 50 mg, and according to the patient's tolerance, it was increased to 25 to 50 mg orally within two weeks, and placebo was prescribed for the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion in the study: Patient consent to enter the study, patients with a mild concussion with a consciousness quotient between 13-15 Exclusion criteria: patients with a history of any brain disorders, bipolar patients with a family history, patients with long QT and a history of arrhythmia, patients with a history of seizures, a history of headaches and mood disorders

##### Intervention groups

In the intervention group: Amitriptyline starts at 10 mg and continues to 50 mg and increases to 25 to 50 mg orally within two weeks. In the control group: Plainbo is prescribed (there is no approved treatment for the disease and does not use any specific drug.

##### Main outcome variables

Headache and sleep disorders

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230627058603N1**

Registration date: **2024-01-03, 1402/10/13**

Registration timing: **retrospective**

Last update: **2024-01-03, 1402/10/13**

Update count: **0**

##### Registration date

2024-01-03, 1402/10/13

##### Registrant information

##### Name

Mehdi Shafiei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3670 0666

##### Email address

neurosurgery\_resident@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-01, 1402/05/10

##### Expected recruitment end date

2023-09-01, 1402/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effectiveness of amitriptyline in preventing headache and sleep disorders in patients with mild brainstorming

**Public title**

Amitriptyline headache and sleep disorders in patients with mild stroke

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient satisfaction to enter the study Patients with mild strokes with a consciousness coefficient of between 13-15

**Exclusion criteria:**

Patients with moderate and high brain trauma Patients with a history of any brain disorders Bipolar and family history Patients with long QT and arrhythmia history Seizure A history of headaches and mood disorders Incidence of any drug complications

**Age**

No age limit

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Easy sampling methods from those who are eligible to enter the study are randomly divided into two groups of cases and control. In this study, the segmentation of individuals is performed as a quadruple block. In this method A reflects the person who receives the intervention and B represents the person in the control group. Considering the four -block block, we give the AABB Code 0, to the ABAB Code 1, to ABBA Code 2, to BAAB Code 3, to BBAA Code 4 and BABA Code 5 to 9. Then, using the random numbers table, select the starting point randomly and then consider the numbers in a row or column. Considering the order of the table numbers, we replace each number we have hit. Finally, 110 people will be divided into two groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher does not know which patient received which medicine. In this study, the placebo is just like the original drug and the patient is unaware of which drug he is taking.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

**Street address**

Hazar Jarib Street, Azadi Square

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2022-04-23, 1401/02/03

**Ethics committee reference number**

IR.MUI.MED.REC.1401.028

**Health conditions studied****1****Description of health condition studied**

Mild brain trauma

**ICD-10 code**

S06.2

**ICD-10 code description**

Diffuse traumatic brain injury

**Primary outcomes****1****Description**

Headache

**Timepoint**

6 months after intervention

**Method of measurement**

HDI Standard Headache Questionnaire

**2****Description**

sleep disorders

**Timepoint**

6 months after intervention

**Method of measurement**

Pittsburgh's sleep quality questionnaire

**Secondary outcomes**

empty

## Intervention groups

1

### Description

Intervention group: Amitriptyline from Daropakhsh pharmaceutical company started with a dose of 10 mg and continued up to 50 mg, and according to the patient's tolerance, it was increased to 25 to 50 mg orally within two weeks. Medication lasts for three months

### Category

Prevention

2

### Description

Control group: Plainboast is prescribed. Medication takes over three months. The manufacturer of placebo is Abidi Pharmaceuticals.

### Category

Prevention

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Al-zahra Hospital

#### Full name of responsible person

Mehdi Shafiei

#### Street address

Al-Zahra Hospital, Safa Street

#### City

Esfahan

#### Province

Isfahan

#### Postal code

8174675731

#### Phone

+98 913 310 1971

#### Email

Mehdishafiei82@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Gholamreza Asgari

#### Street address

Hazar Jarib Street, Azadi Square

#### City

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#### Province

Isfahan

#### Postal code

81746-73461

#### Phone

+98 31 3668 0048

#### Email

mui@mui.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Esfahan University of Medical Sciences

### Proportion provided by this source

1

### 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

Esfahan University of Medical Sciences

#### Full name of responsible person

Mehdi Shafiei

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Neurosurgery

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Hazar Jarib Street, Azadi Square

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Mehdi Shafiei

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Neurosurgery  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mehdi Shafiei  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable