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)
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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
Isfehan
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: Plainboat 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
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Al-Zahra Hospital, Safa Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Phone
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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
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Person responsible for updating data

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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