Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparing the effect of Acetazolamide and Topiramate on patients with traumatic cerebrospinal fluid leakage

Protocol summary

Study aim
Cessation of cerebrospinal fluid leakage caused by brain trauma

Design
In the random block method, people are divided into two groups, and then medication is administered by the clinical caregiver with a specific code for them, and it is provided to the researcher (student). The researcher evaluates the patients using a questionnaire and records the results based on the patient code. Patients are also not aware of the type of surgery. Also, the analyzer is not aware of the group in which the patient is placed.

Settings and conduct
This study is a blinded clinical trial that will be conducted in Kashani Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient consent to enter the study The patient's non-use of Tricyclic Antidepressants and carbonic anhydrase inhibitor in order to prevent drug interactions. Exclusion criteria: Patients who develop meningitis and brain abscess Patients with severe electrolyte disturbances Patients who do not respond to treatment and have to use brain surgery Patients who did not respond to drug therapy after one week and another intervention should be performed on them Failure to visit the patient for follow-up Kidney and liver patients who are suffering from a specific disease based on the diagnosis of a specialist and are listed in the patient's medical record

Intervention groups
In the intervention group, acetazolamide will be administered at a dose of 1 gram per day, and in the control group, topiramate will be administered at a dose of 100 mg per day.

Main outcome variables
Cessation of cerebrospinal fluid leakage caused by brain trauma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221108056446N4**
Registration date: **2023-11-15, 1402/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-15, 1402/08/24**
Update count: **0**

Registration date
2023-11-15, 1402/08/24

Registrant information

Name
Mehdi Mahmoodkhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 686 3733

Email address
mahmoodkhani@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of Acetazolamide and Topiramate on patients with traumatic cerebrospinal fluid leakage

Public title
Acetazolamide and Topiramate on patients with traumatic cerebrospinal fluid leakage
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient consent to enter the study The patient's non-use of Tricyclic Antidepressants and carbonic anhydrase inhibitor in order to prevent drug interactions.
Exclusion criteria:
Patients who develop meningitis and brain abscess Patients with severe electrolyte disturbances Patients who do not respond to treatment and have to use brain surgery Patients who did not respond to drug therapy after one week and another intervention should be performed on them Failure to visit the patient for follow-up Kidney and liver patients who are suffering from a specific disease based on the diagnosis of a specialist and are listed in the patient's medical record
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
People are placed in 2 groups by random block method. In this way, the first 2 eligible people are selected and after obtaining consent, they enter to participate in the study. These 2 people are considered as a block of 2 and are sorted according to the last digit of the national code. The treatment methods are specified as A, B, and all combinations of 2 are specified, and after the last surgery, decoding is done for the last block.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Hazar Jarib Street, Azadi Square
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-08-14, 1402/05/23
Ethics committee reference number
IR.ARI.MUI.REC.1402.125

Health conditions studied

1

Description of health condition studied
Brain Trauma
ICD-10 code
S06.2
ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Cerebrospinal fluid leakage
Timepoint
Patients are evaluated weekly using a checklist and up to three months after discharge from the hospital.
Method of measurement
Checklist and measurement of GCS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They receive 1 gram of acetazolamide in oral form every 24 hours, which will continue for 5-7 days
Category
Treatment - Drugs

2

Description
Control group: They receive 100 mg topiramate orally every 24 hours, which will continue for 5-7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani Hospital
Full name of responsible person
Mehdi Mahmoodkhani
Street address
Kashani St
City
Isfahan
Province
Isfehan
Postal code
83434-81839
Phone
+98 31 3233 0091
Email
kashani@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Esfahan University of Medical Sciences
Street address
Hazar Jarib Street, Azadi Square
City
Isfahan
Province
Isfehan
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 Mahmoodkhani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Kashani street
City
Esfahan
Province
Isfehan
Postal code
83434-81839
Phone
+98 31 3233 0091
Email
mahmoodkhani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Mahmoodkhani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Kashani street
City
Esfahan
Province
Isfehan
Postal code
83434-81839
Phone
+98 31 3233 0091
Email
mahmoodkhani@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Mahmoodkhani
Position
Assistant Professor

Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Kashani street
City
Esfahan
Province
Isfehan
Postal code
83434-81839
Phone
+98 31 3233 0091
Email
mahmoodkhani@med.mui.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available