

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of phenytoin and Levetiracetam and valproic acid in prevention of seizure of post traumatic brain hemorrhage

Protocol summary

Study aim

Comparing the effectiveness of phenytoin, Levetiracetam, and valproic acid in preventing seizures in hemorrhage caused by brain trauma.

Design

Clinical trial with 3 intervention groups, with parallel groups, Double-blind, randomized, phase 3 on 225 patients. Block method was used for randomization with randomization.com online software.

Settings and conduct

225 brain trauma patients referred to Valiasr Hospital in Arak city, who were randomly divided into 3 groups and received one of the 3 commonly used injectable anticonvulsant drugs available in Iran. Then they will be evaluated within the first 24 hours and then up to 6 days. This study is double-blind and the patients or their legal guardians and the intern are not aware of the type of drug received, but the project manager and the analyzer will be aware of the type of drug received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: head trauma that requires prophylactic anticonvulsant treatment. Exclusion criteria: pregnancy, History of epilepsy, history of allergy to studied drugs.

Intervention groups

In the first intervention group, patients are treated with phenytoin with a loading dose of 20 mg/kg and injection within one hour and a maintenance dose of 5 mg/kg every day. First, they receive injectable medicine for 24 to 48 hours and then oral medicine. The second group: treatment with the drug Levetiracetam with a loading dose of 20 mg/kg and injection within one hour and a maintenance dose of 10 to 20 mg/kg per day. Patients first receive injectable medicine for 24 to 48 hours and then oral medicine. The third group: First, 15 mg/kg sodium valproate is administered by injection, and a maintenance dose of 15 mg/kg is administered in 2 to 3 divided doses every day. The patient first receives

injectable medicine for 24 to 48 hours and then oral medicine.

Main outcome variables

Number of seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240617062155N1**

Registration date: **2024-08-10, 1403/05/20**

Registration timing: **registered_while_recruiting**

Last update: **2024-08-10, 1403/05/20**

Update count: **0**

Registration date

2024-08-10, 1403/05/20

Registrant information

Name

benyamin beyrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4417 3304

Email address

benyamin.medicine@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-01, 1403/05/11

Expected recruitment end date

2024-09-30, 1403/07/09

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of phenytoin and Levetiracetam and valproic acid in prevention of seizure of post traumatic brain hemorrhage

Public title
effectiveness of phenytoin and Levetiracetam and valproic acid in prevention of seizure of brain hemorrhage

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Head trauma requiring prophylactic anticonvulsant treatment
Exclusion criteria:
Pregnancy History of epilepsy Allergy to the studied drugs

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **225**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study will be done using block randomization method. In this way, 225 blocks of 3 were created randomly using randomization.com online software by the plan's statistical consultant and sealed in 225 envelopes with aluminum cover and numbered in the order of creation. Then, during the implementation of the plan, the created sequences will be removed from the envelopes and the patients will be assigned to groups A, B and C based on the sequence of each block.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will be assigned to each treatment based on block randomization method. The study procedure and the requirement to receive an anticonvulsant drug after severe traumatic brain injury, which is one of the 3 injectable drugs available in Iran which are also the subject of our study, will be explained to patients or their legal guardians, and informed consent will be obtained. However, the patients or their legal guardian will not be aware of the type of drug received (out of the 3 drugs). Additionally, the medical intern, who is responsible for collecting data, will not be aware of the drug received

and will recognize them into groups A, B, or C ; the project manager and the data analyst will be aware of the type of drug received by the patients.

Placebo
Not 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
Payambar-e-azam complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2024-05-18, 1403/02/29
Ethics committee reference number
IR.ARAKMU.REC.1403.051

Health conditions studied
1
Description of health condition studied
traumatic intracerebral haemorrhage
ICD-10 code
S06.3
ICD-10 code description
Focal traumatic brain injury

Primary outcomes
1
Description
Seizure
Timepoint
The first day to a week after starting the study
Method of measurement
Clinical observation

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group 1: In this group, the patients are treated with the anticonvulsant drug phenytoin (Caspian-Iran) with a loading dose of 20 mg/kg and injection within one hour and a maintenance dose of 5 mg/kg every day, which the patients first receive injectable drug for 24 to 48 hours and then They receive oral drug. Phenytoin is taken from Caspian Tamin-Iran pharmaceutical company. It is one of the three common anti-seizure medications used in Iran to prevent seizures caused by traumatic brain injury

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, patients are treated with the anticonvulsant drug Levetiracetam (Arang-Iran) with a loading dose of 20 mg/kg and an injection within one hour and a maintenance dose of 10 to 20 mg/kg every day. They receive for 24-48 hours injectable and then oral medicine. Levetiracetam is taken from Arang-Iran Daro Darman pharmaceutical company . It is one of the three common anti-seizure medications used in Iran to prevent seizures caused by traumatic brain injury

Category

Treatment - Drugs

3

Description

Intervention group 3: In this group, 15 mg/kg of the anticonvulsant drug sodium valproate (Arang-Iran) injection is first prescribed for patients, and the maintenance dose is 15 mg/kg in 2 to 3 divided doses every day. Patients first receive injectable medicine for 24 to 48 hours and then orally. The sodium valproate is taken from Daro Derman Arang-Iran pharmaceutical company. It is one of the three common anti-seizure medications used in Iran to prevent seizures caused by traumatic brain injury

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Benyamin Beyrami

Street address

Valiasr sq.

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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

Davud Hekmatpou

Street address

Payambar-e-azam complex, Sardasht Town

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research@arakmu.ac.ir

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

Benyamin Beyrami

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Benyamin Beyrami

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

A Level or less

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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

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