Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

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)

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+98 86 4417 3304

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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 hemorrahage

Public title

effectiveness of phenytoin and Levetiracetam and valproic acid in prevention of seizure of brain hemorrahage

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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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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