

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of prophylactic intravenous or oral levetiracetam and phenytoin in delay post trauma seizure

Protocol summary

Study aim

prophylactic intravenous or oral levetiracetam and phenytoin in delay post trauma seizure

Design

The present study is a randomized controlled trial study of double-blind control. The target population of this study is patients who complain of head trauma to the hospital and are candidates for anticonvulsant prophylaxis and express their consent to participate in the trial in writing. Criteria for initiating anticonvulsant prophylactic treatment for patients based International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) is. In each group, 60 patients will be randomly assigned.

Settings and conduct

The study will be conducted at Al-Zahra and Kashani Hospitals in Isfahan, where patients with traumatic brain injury are randomly divided into two groups and are treated with medication.

Participants/Inclusion and exclusion criteria

entry criteria; Head trauma that requires antiretroviral prophylaxis treatment, for example, the patient has hypertensive depression or intracerebral hemorrhage. The patient must be at least 18 years old exit criteria: Pregnancy, Previous history of epilepsy, Previous history of seizures after trauma to the head, Sensitivity, Late visit to the hospital 12 hours after the trauma

Intervention groups

The intervention group in this technical trial of Twain is treated with a loading dose of 20mg/kg and injection within one hour and a maintenance dose of 5 mg/kg/day, which the patient first receives for 24 to 48 hours after the injection and then orally. The control group is treated with lootrastam with a loading dose of 20mg/kg and injection within one hour and a maintenance dose of 10-20 mg/kg/day, which the patient first receives for 24 to 48 hours and then oral administration.

Main outcome variables

Late seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200415047090N1**

Registration date: **2020-07-26, 1399/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-26, 1399/05/05**

Update count: **0**

Registration date

2020-07-26, 1399/05/05

Registrant information

Name

Saeid Saghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3624 6796

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic intravenous or oral levetiracetam and phenytoin in delay post trauma seizure		Secondary Ids
		empty
Public title	prophylactic intravenous or oral levetiracetam and phenytoin in delay post trauma seizure	Ethics committees
Purpose	Treatment	<u>1</u>
Inclusion/Exclusion criteria	Inclusion criteria: Head trauma that requires antiretroviral prophylaxis treatment, for example, the patient has hypertensive depression or intracerebral hemorrhage (IntraCerebral Hemorrhage, Intraventricular hemorrhage, Subarachnoid hemorrhage). The patient must be at least 18 years old Sign a written consent to participate in the study Exclusion criteria: Pregnancy Previous history of epilepsy Previous history of seizures after trauma to the head Taking other anticonvulsant drugs	Ethics committee
Age	From 18 years old	Name of ethics committee Ethics committee of Esfahan University of Medical Sciences
Gender	Both	Street address Isfahan University of Medical Sciences, Hezar Jarib St., Shiraz Gate,
Phase	N/A	City Esfahan
Groups that have been masked	- Participant - Investigator	Province Isfahan
Sample size	Target sample size: 160	Postal code ۷۳۴۶۱-۸۱۷۴۶
Randomization (investigator's opinion)	Randomized	Approval date 2020-05-30, 1399/03/10
Randomization description	In order to randomly assign patients, a randomized block allocation method with a volume of 4 patients in each block will be used. The third person independent of the study, based on the random block method, provides a list of 160 randomly coded codes and provides it to the research team along with 160 coded envelopes. Eligible patients enter the list and, based on the numerical code listed in the envelope list, open the code that corresponds to the numeric code listed in the list and inject the encoded drug into the patient.	Ethics committee reference number IR.MUI.MED.REC.1398.501
Blinding (investigator's opinion)	Double blinded	Health conditions studied
Blinding description	In this study, after explaining the goals to the patient, he is given informed consent. Patients are randomly divided into two groups, but neither group is aware of which group. The researcher does not know which group each patient belongs to. However, the clinical caregiver is aware of the group of patients and uses the drug in accordance with the group in which the patient is placed.	<u>1</u>
Placebo	Not used	Description of health condition studied Head traumatic injury
Assignment	Parallel	ICD-10 code G44.3
Other design features		ICD-10 code description Post-traumatic headache
		Primary outcomes
		<u>1</u>
		Description Intracranial hemorrhage
		Timepoint 7 day
		Method of measurement Patient seizures and other clinical symptoms
		Secondary outcomes
		empty
		Intervention groups
		<u>1</u>
		Description Intervention group: Phenytoin is treated with a loading dose of 20 mg / kg and injection within one hour and a maintenance dose of 5 mg / kg / day, which the patient first receives for 24 to 48 hours after injection and then orally.

Category

Treatment - Drugs

2**Description**

Control group: Lothirastam is treated with a 20 mg / kg loading and injection within an hour and a maintenance dose of 10-20 mg / kg / day, which the patient first receives for 24 to 48 hours after the injection and then orally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra hospital

Full name of responsible person

Dr Mehdi Shafiei

Street address

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Boulevard

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2**Recruitment center****Name of recruitment center**

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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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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

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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Shafiei

Position

Assistant Professor

Latest degree

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable