

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Study the effect of co-administration of an acid juice (Orange juice) with phenobarbital on its serum level in pediatric with seizure

Protocol summary

Summary

The aim of this study was to evaluate the efficacy of orange juice with phenobarbital on its serum level as an anti-seizure drug. This double-blind clinical trial was performed on 40 patients with seizure referring to Hashemtaieh Sabzevar Educational Research Center in 1396. Patients were randomly divided into two groups. After controlling seizure with a specific intravenous phenobarbital drug (10 milligram per kilogram body weight), then to a group of phenobarbital medications with orally (2.5 milligram per kilogram body weight) with Normal water and another group was given with orange juice. Two blood samples were taken from the patient as soon as the drug was taken and then two hours after the oral dose of the drug and taken for centrifuge and then freezing into the hospital laboratory. Samples were sent to the laboratory of the School of Hygiene to determine the surface by HPLC.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062519240N3**

Registration date: **2017-10-21, 1396/07/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-21, 1396/07/29

Registrant information

Name

Omid Gholami

Name of organization / entity

Sabzevar University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2017-09-21, 1396/06/30

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of co-administration of an acid juice (Orange juice) with phenobarbital on its serum level in pediatric with seizure

Public title

Study the effect of co-administration of Orange juice with phenobarbital on its serum level

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children with seizures without fever who have had seizures for the first time; Children with fever and seizures that have seizures lasting more than 15 minutes; Children with fever and seizures that have recurring seizures within 24 hours; Children with fever and seizures that have a seizure with focal manifestations exclusion criteria: Dissatisfaction with the continuation of the plan at any stage of the plan; A child who has had a history of taking phenobarbital in the

past; A child with a history of taking any anticonvulsant medication; The infant with her mother is taking a seizure that takes medicine; Children who are over 10 milligram per kilogram for lack of control of seizures receive an initial dose of intravenously.

Age

To 20 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Samples were randomly divided into case and control groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Shohada hastee street, Sabzevar, Iran

City

Sabzevar

Postal code

Approval date

2017-08-30, 1396/06/08

Ethics committee reference number

IR.MEDSAB.REC.1396.59

Health conditions studied

1

Description of health condition studied

seizure

ICD-10 code

G40

ICD-10 code description

seizure ,Epilepsy

Primary outcomes

1

Description

Serum levels of phenobarbital

Timepoint

Two hours after the intervention

Method of measurement

HPLC machine based on milligram per deciliter

Secondary outcomes

1

Description

Tonic Clonic Movement of the Patient

Timepoint

An hour after the intervention

Method of measurement

Direct observation and clinical examination

Intervention groups

1

Description

Intervention group: Phenobarbital with a dose of 2.5 milligram / kilogram body weight orally with orange juice

Category

Treatment - Drugs

2

Description

Control group: Phenobarbital with a dose of 2.5 milligram / kilogram body weight orally with normal water

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashmatyee Hospital in Sabzevar

Full name of responsible person

Morteza Tavasolizadeh

Street address

Sabzevar University of Medical Sciences

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Sabzevar University of Medical Sciences

Full name of responsible person

Mohamad Mohamadzadeh

Street address

Sabzevar University of Medical Sciences, Deputy of Research and Technology

City

Sabzevar

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research of Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

MortezaTavasolizadeh

Position

Student

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Sabzevar University of Medical Sciences

Full name of responsible person

Dr Omid Gholami

Position

Assistant Professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty