

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of oral Vit B6 on behavioral disorders due to Phenobarbital.

Protocol summary

Summary

Objective: Effectiveness of oral Vit B6 on behavioral disorders due to Phenobarbital. Design: In this interventional study, a total of 100 consenting patients will be selected and divided in to intervention and control groups using block randomization method (n=50 in each group). Proper counseling to parents patients will be done and a written informed consent will be obtained before starting the treatment regimen. Inclusion criteria: Use of phenobarbital, ages 2 to 15 years. Exclusion criteria: Another antiepileptic medication with phenobarbital. Setting and conduct: At baseline, for all patients, behavioral patterns (aggressive behavior, attention and more hyperactivity disorder) in the questionnaire containing demographic and disease information is recorded. In the intervention group, patients will be received oral Vit B6 (100 mg every 24 hours for 3 months produced by Osve CO) and oral phenobarbital (3-5 mg/kg every 24 hours for 3 months produced by Pars daroo CO). In the control group, patients will be received oral placebo (every 24 hours for 3 months produced by Osve CO) and oral phenobarbital (3- 5 mg/kg every 24 hours for 3 months produced by Pars daroo CO). After three months children's behavior will be assessed and results will be analyzed. Outcomes measure: Aggressive behavior, attention and more hyperactivity disorder.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407284676N4**

Registration date: **2017-06-17, 1396/03/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-17, 1396/03/27

Registrant information

Name

farzad ahmadabadi

Name of organization / entity

Ardabil University of Medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of oral Vit B6 on behavioral disorders due to Phenobarbital.

Public title

Effect of vitamin B6 on behavioral disorders due to Phenobarbital.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Use of phenobarbital, ages 2 to 15 years; Exclusion criteria: Another antiepileptic medication with phenobarbital

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medicine Sciences Ethics committee

Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City

Ardabil

Postal code

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

IR.ARUMS.REC.1394.5

Health conditions studied

1

Description of health condition studied

Seizure

ICD-10 code

G40

ICD-10 code description

Generalized idiopathic epilepsy and epileptic syndromes

Primary outcomes

1

Description

aggressive behavior

Timepoint

At baseline and three months after intervention

Method of measurement

Conners criteria

Secondary outcomes

1

Description

Hyperactivity disorder

Timepoint

At baseline and three months after intervention

Method of measurement

Conners criteria

2

Description

Attention

Timepoint

At baseline and three months after intervention

Method of measurement

Conners criteria

Intervention groups

1

Description

Intervention group: patients will be received oral Vit B6 (100 mg every 24 hours for 3 months produced by Osve CO) and oral phenobarbital (3-5 mg/kg every 24 hours for 3 months produced by Pars daroo CO)

Category

Treatment - Drugs

2

Description

Control group: patients will be received oral placebo (every 24 hours for 3 months produced by Osve CO) and oral phenobarbital (3- 5 mg/kg every 24 hours for 3 months produced by Pars daroo CO).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Child neurology clinic of Ardabil university of medical sciences

Full name of responsible person

Dr. Farzad Ahmadabadi

Street address

Child neurology clinic of Ardabil university of medical sciencesl, Moallem street, Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr. Shahram Habibzadeh

Street address

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

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Ardabil

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

Yes

Title of funding source

Vice chancellor for research, Ardabil 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

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Position

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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