

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Comparisson of the effect of Zonisamide and Pregabalin as adjunctive therapy in control of interactable epilepsy in children

Protocol summary

Summary

Zonisamide drug known as an anticonvulsant drug with a wide spectrum of function. Zonisamide is effective in controlling of partial and generalized seizures. Pregabalin has anticonvulsant effect like Gabapentine. In previous studies what has been less evaluated is that these two drugs did not compared in view of their efficacy on pediatric interactable epilepsy. In this study ninty six children with seizures which admitted to Mofid Children Hospital and despite taking two or three anti-seizure medication, have uncontrolled seizure ,and have no neurodegenerative diseases has been randomly divided into two groups and the first group will be treated with Zonisamide while the second group will be treated with Pregabalin and after one month and six months since drug starting reduction of the frequency and severity of seizures are analyzed. During the follow-up over fifty percent reduction in seizure frequency or severity is known as a response to drug .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091210508N4**

Registration date: **2012-10-20, 1391/07/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-20, 1391/07/29

Registrant information

Name

MohammadKazem Bakhshandeh Bali

Name of organization / entity

Shahid Beheshti medical university

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 9625

Email address

dr.mk.bakhshandehbali@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti Medical University

Expected recruitment start date

2012-04-01, 1391/01/13

Expected recruitment end date

2012-11-01, 1391/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisson of the effect of Zonisamide and Pregabalin as adjunctive therapy in control of interactable epilepsy in children

Public title

Effect of Zonisamide and Pregabalin in control of interactable epilepsy in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children one to eighteen years; having resistant epilepsy; referred to Mofid Children's Hospital
Exclusion criteria: children with neurodegenerative diseases

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak , Tehran

City

Tehran

Postal code

Approval date

2012-09-06, 1391/06/16

Ethics committee reference number

1391-1-146-1010

Health conditions studied

1

Description of health condition studied

Interactable epilepsy

ICD-10 code

G40

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Seizure

Timepoint

1 and 6 months later

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups

1

Description

Ninety six children with seizures which admitted to Mofid children hospital and despite taking two or three anti-seizure medication, have uncontrolled seizure and have no neurodegenerative diseases has been randomly divided into two groups (1 and 2) and the group 1 will be treated with Zonisamaide orally with dose of 2 - 12 miligram per kilogram daily and after one month and six months since drugs starting reduction of the frequency and severity of seizures are analyzed and compared with group 2. During the follow-up over fifty percent reduction in seizure frequency or severity is known as a response to drug .

Category

Treatment - Drugs

2

Description

Ninety six children with seizures which admitted to Mofid children hospital and despite taking two or three anti-seizure medication, have uncontrolled seizure and have no neurodegenerative diseases has been randomly divided into two groups (1 and 2) and the group 2 will be treated with Pregabalin orally with dose of 5-15 miligram per kilogram daily and after one month and six months since drugs starting reduction of the frequency and severity of seizures are analyzed and compared with group 1. During the follow-up over fifty percent reduction in seizure frequency or severity is known as a response to drug .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric neurology research center

Full name of responsible person

Dr Mohammad Kazem Bakhshandeh Bali

Street address

No. 25 , Kamyar Lane , Shariati street , Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science
Full name of responsible person
Dr Ghofrani
Street address
No. 25 , Kamyar Lane , Shariati street , Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Science
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

Pediatric neurology research center

Full name of responsible person

Dr Mohammad Kazem Bakhshandeh Bali

Position

Pediatric neurology fellow

Other areas of specialty/work**Street address**

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Dr.MK.Bakhshandehbali@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Institute of Child Neurology

Full name of responsible person

Dr Ghofrani

Position

Professor of Child Neurology

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Pediatric neurology research center

Full name of responsible person

Dr Mohammad Kazem Bakhshandeh Bali

Position

Pediatric neurology fellow

Other areas of specialty/work**Street address**

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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