

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Efficacy of Zonisamide in the treatment of children with refractory epilepsy coming to Mofid children hospital

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. In previous studies what has been less evaluated is that how Zonisamide administration can treat pediatric resistant epilepsy. In this study children 1 to 18 years old with seizures which admitted to Mofid children Hospital and despite taking two or three anti-seizure medication, have uncontrolled seizure and do not have neurodegenerative diseases has been treated with Zonisamide and after one month and six months of 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: **IRCT2012091210508N2**

Registration date: **2012-10-09, 1391/07/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-09, 1391/07/18

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

Pediatric neurology nesearch center of Shahid Beheshti medical university

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2012-10-01, 1391/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Zonisamide in the treatment of children with refractory epilepsy coming to Mofid children hospital

Public title

Efficacy of Zonisamide in the treatment of children with refractory epilepsy

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: 67

Randomization (investigator's opinion)

N/A

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

2012-09-16, 1391/06/26

Ethics committee reference number

1391-1-146-9591-10230

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 after drug starting

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups

1

Description

Children with seizures which admitted to Mofid children hospital and despite taking two or three anti-seizure medication, have uncontrolled seizure, and do not have neurodegenerative diseases, has been treated with Zonisamide (2 - 12 mg/kg/day) 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 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**

تهران - شریعتی - روبروی حسینیه ارشاد - کوچه کامیار پلاک 25

City

تهران

Postal code**Phone**

+212 2259625

Fax**Email**

Dr.MK.Bakhshandehbali@sbmu.ac.ir

Web page address**Email**

Pkarimzadeh@yahoo.com

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**

No. 25 , Kamyar Lane , Shariati street , Tehran

City

Tehran

Postal code**Phone**

+98 21 2225 9625

Fax**Email**

Dr.MK.Bakhshandehbali@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pediatric neurology research center

Full name of responsible person

Dr Parvaneh Karimzadeh

Position

Pediatric neurologist

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

No. 25 , Kamyar Lane , Shariati street , Tehran

City

تهران

Postal code**Phone**

+212 2259625

Fax

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