

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Summary

Pregabalin drug known as an anticonvulsant drug with a wide spectrum of function. Pregabalin is effective in controlling of partial and generalized seizures .In this study sixty 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 Pregabalin 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: **IRCT2012101510508N5**

Registration date: **2012-10-21, 1391/07/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-21, 1391/07/30

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 University of Medical Sciences

Expected recruitment start date

2011-10-01, 1390/07/09

Expected recruitment end date

2012-10-02, 1391/07/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Efficacy of Pregabalin 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

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

1391-1-146-1009

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

oral Pregabalin (5- 15 mg/kg/day)

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 Sciences

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 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**

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 Ghofrani

Position

Pediatric neurologist

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 updating data****Contact****Name of organization / entity**

Pediatric neurology research center

Full name of responsible person

Dr Mohammad Kazem Bakhshandeh

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**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