

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of efficacy of pregabalin in the treatment of refractory partial seizures in children and adolescents under 18 years

Protocol summary

Summary

Pregabalin is one of the latest additions in the antiepileptic medications that are used in the treatment of refractory partial seizures in childhood. This 12-weeks, Open-labeled, before-after study is performed on children and adolescents under 18 years old age and evaluates the efficacy of pregabalin to reduce seizures frequency in these patients who suffering from refractory partial seizures. Exclusion criteria were included: current treatment with Vigabatrin or Felbamate; patients that having absence seizure, status epilepticus, Lennox syndrome and myoclonic seizure; renal failure; patients who suffering from neurometabolic or progressive neurologic disorders. Sample size based on statistical methods was about 30 patients. This study comprised three main phases; after selecting the patients and before the onset of the treatment period, in a period of 6 weeks (baseline phase), Average daily and weekly seizure of the patients were recorded by the patient, a trained observer or a legal guardian. After that, during a period of 2 weeks (dose-optimization phase), drug was started with a flexible dose of 25-75 mg/d TID or BID and then reached to maximum dose of 450 mg/d based on clinical response of the patient. In the next 12 weeks (observation phase) the patients were given the drug and the average daily and weekly patient's seizures were recorded again. Responder rate and RRatio of the patients at the end of the study were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206099982N1**

Registration date: **2012-08-09, 1391/05/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-09, 1391/05/19

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences ,Private Sector

Expected recruitment start date

2011-07-02, 1390/04/11

Expected recruitment end date

2011-09-02, 1390/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of pregabalin in the treatment of refractory partial seizures in children and adolescents under 18 years

Public title

Efficacy of pregabalin in control of seizures in children and adolescents

Purpose

Treatment

Inclusion/Exclusion criteria

This study is performed on children and adolescents under 18 years old. Sexuality of the patient is not important for entrance to this study. Inclusion criteria are included: Patients aged under 18 years with a diagnosis of refractory partial seizures (namely if the seizure was not adequately controlled by one to three AEDs administered as monotherapy or in combination before entering the study); All patients with a minimum of 4-6 partial seizures in the baseline phase of the study; patient never had a maximum of 28 free seizure days in the baseline phase of the study. Exclusion criteria are included: current treatment with Vigabatrin or Felbamate; patients that having absence seizure, status epilepticus, Lennox syndrome and myoclonic seizure; renal failure; patients who suffering from neurometabolic or progressive neurologic disorders.

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: **26**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science, Research deputy, Ethics Committee

Street address

Keshavarz blvd, next the ghods street, Tehran

City

Tehran

Postal code

Approval date

2012-07-14, 1391/04/24

Ethics committee reference number

130/801/91/ص

Health conditions studied

1

Description of health condition studied

Refractory epilepsy

ICD-10 code

G40.O,G40.

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Evaluation of efficacy of pregabalin in the treatment of refractory partial seizures in children and adolescents

Timepoint

At baseline period- At the end of treatment period

Method of measurement

RRatio(The mean seizure frequency in a 28 days period at the onset and end of the treatment period)

Secondary outcomes

1

Description

The percentage of patients who have not had a good clinical response; the percentage of the known complications of pregabalin among patients and determine the percentage of each side effects separately; determine the percentage of drug discontinuation among patients due to side effects or ineffectiveness separately; the retention rate or number of patients who are still being received Pregabalin for part or all of the treatment period ; classification of seizure type in patients based on two groups: idiopathic and symptomatic

Timepoint

at the end of weeks:2,4,8,12 during treatment period

Method of measurement

measured based on percentage

Intervention groups

1

Description

This 12-week, Open-labeled, before-after study comprised three main phases; after selecting the patients and before the onset of the treatment period, in a period of 6 weeks (baseline phase), Average daily and weekly seizure of the patients were recorded by the patient, a trained observer or a legal guardian. After that, during a period of 2 weeks (dose-optimization phase), drug was started with a flexible dose of 25-75 mg/d TID or BID and then reached to maximum dose of 450 mg/d based on clinical response of the patient. In the next 12 weeks (observation phase) the patients were

given the drug and the average daily and weekly patient's seizures were recorded again. Desired outcome of the study to decrease the seizure frequency of the patient by 50% compared to baseline period.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children Medical Center

Full name of responsible person

Dr Alireza tavasoli, Dr Gholamreza zamani

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Private

Full name of responsible person

Dr Alireza tavasoli, Dr Gholamreza zamani

Street address

Pediatric neurology ward, Children medical center,
Gharib Avenue, Keshavarz blvd

City

Tehran

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

Yes

Title of funding source

Private

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**

Children Medical Center

Full name of responsible person

Dr Alireza tavasoli

Position

Fellow of pediatric neurology

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Children Medical Center

Full name of responsible person

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Fellow of pediatric neurology

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>