# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 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 next12 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**
Alireza Tavasoli
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**Recruitment status**

**Recruitment complete**


**Funding source**

Tehran University of Medical Sciensces ,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 duo 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**
weasured 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 next12 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**

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## Person responsible for scientific inquiries

**Contact**

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**Other areas of specialty/work**

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## 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*