

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

pregabalin in childhood epilepsy: clinical trial in qom and tehran

Protocol summary

Summary

Seizure is very important in childhood age. Prevalence of seizure is about 0/5 to 1 percent. About 25% of these patients don't respond to treatments and known as refractory seizures. There are many drugs for epilepsy. Some of them cure and some reduce the frequency or intensity of seizures. Pregabalin is a new antiepileptic drug. There are a few studies with PGB in children. In this study we prescribed PGB in refractory childhood epilepsy.

General information

Acronym

pregabalin:PGB

IRCT registration information

IRCT registration number: **IRCT2014012216320N1**

Registration date: **2014-05-23, 1393/03/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name

Mohsen Mollamohammadi

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3260 3518

Email address

dr.mmohamadi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom university of medical science

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-09-06, 1393/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

pregabalin in childhood epilepsy: clinical trial in qom and tehran

Public title

pregabalin in childhood epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with refractory seizure

Exclusion criteria: patients with myoclonic seizures; sensitivity to PGB; patients that received gabapentin.

Age

From **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Qom university of medical science

Street address

Shahid lavasany ave. qom

City

Qom

Postal code

371697115

Approval date

2014-05-03, 1393/02/13

Ethics committee reference number

MUQ.REC.1393.4

Health conditions studied

1

Description of health condition studied

Seizure

ICD-10 code

G40

ICD-10 code description

Attack with loss of consciousness

Primary outcomes

1

Description

Decrease count of seizure

Timepoint

One and four month after intervention

Method of measurement

Counting

2

Description

Decrease intensity of seizure

Timepoint

One and four month after intervention

Method of measurement

Asking from parents

Secondary outcomes

1

Description

Drug reaction

Timepoint

One and four month after intervention

Method of measurement

Questionair

Intervention groups

1

Description

Pregabalin used as add on therapy in childhood epilepsy. cap.25-50-75-100-150 mg.10mg/kg/day.2-3 time/day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat masomeh hospital-Qom

Full name of responsible person

Dr. molla mohammadi

Street address

Emam khomeiny ave.

City

Qom

2

Recruitment center

Name of recruitment center

Mofid hospital--Tehran

Full name of responsible person

Dr.mohsen molla mohammadi

Street address

Shariati street.tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Dr. Hosein Saghafi

Street address

No 83, No 4 ave, No 1.1 ave, Safa Shahr. Qom

City

Qom

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Qom 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**

Qom medical university

Full name of responsible person

Mohsen molla mohammadi

Position

Assistant profesor-pediatric neurologist

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

Qom.hazrat masoumeh hospital

City

Qom

Postal code**Phone**

+98 25 3665 1802

Fax**Email**

dr.mmohamadi@muq.ac.ir

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Hasan Tonekabony

Position

Professor

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

Mofid hospital, Shariati street,Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 2241 3017

Fax**Email**

sh.tonekabony@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Qom medical university

Full name of responsible person

Mohsem molla mohammadi

Position

Assistant profesor

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

Hazrat masoumeh hospital-qom

City

Qom

Postal code

3719815539

Phone

+98 25 3665 1802

Fax**Email**

dr.mmohamadi@muq.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