Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

pregabalin in childhood epilepsy: clinical trial in qom and tehran

Protocol summary

Summary

Seizure is very important in chilhood age. Prevalence of seizure is about 0/5 to 1 persent.About 25% of these patients dont responce to tretments 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 study 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 eoilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion critria: all patients with refractory seizure
Exclusion criteria: patients with myoclonic siezures; sensitivty to PGB; patients that recieved 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 mounth 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 interventionque
Method of measurement
Quetionair

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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