

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of two drugs Levetiracetam and Na-valproate in the treatment of generalized tonic clonic seizures in children aged 5-13 years old admitted to Amirkola Hospital

#### Protocol summary

##### Study aim

Comparison of the effect of two drugs Levetiracetam and Na-valproate in the treatment of generalized tonic clonic seizures in children aged 5-13 years old admitted to Amirkola hospital

##### Design

Clinical trials with community based and pragmatic control group, with parallel groups, single blind, randomized,

##### Settings and conduct

Among children aged 5 to 13 years with generalized tonic seizures who visit the Amirkola children's hospital, 60 cases were randomly selected and then randomly divided into two groups. sodium valproate is given to group A and Levetiracetam is given to group B. People eligible for inclusion are not aware of the used drug.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 5 to 13 years old, children Suffering generalized tonic clonic seizure and Exclusion criteria criteria: Electrolyte imbalance in creatinine and blood urea nitrogen, drug sensitivity or appropriate drug intolerance.

##### Intervention groups

Intervention group: Levetiracetam 250 to 500 mg once day for 3 to 6 months. Control group: Sodium valproate 200 to 500 mg once day for 3 to 6 months.

##### Main outcome variables

Recurrence of seizure, EEG, Imaging

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190108042287N1**

Registration date: **2019-02-16, 1397/11/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-16, 1397/11/27**

Update count: **0**

##### Registration date

2019-02-16, 1397/11/27

##### Registrant information

###### Name

Faezeh Bolboli

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3234 6963

###### Email address

f.bolboli@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of two drugs Levetiracetam and Na-valproate in the treatment of generalized tonic clonic seizures in children aged 5-13 years old admitted to Amirkola Hospital

##### Public title

Comparison of the effect of two drugs Levetiracetam and Na-valproate in the treatment of generalized tonic clonic

seizures

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Children aged 5-13 years old Children suffering generalized tonic-clonic seizures

### Exclusion criteria:

Electrolyte imbalance in creatinine and urea nitrogen blood Sensitivity to drug

## Age

From **5 years** old to **13 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The drug Levetiracetam and Na-valproate were placed in two containers A and B and the medicine was given to patients according to a randomized table. The researcher considered the numbers from 0-24 and 25-49 for the Levetiracetam group and the Na-valproate group, respectively. Then, the researcher will select one of the numbers and move in the preset direction and record the numbers and assign them to different groups.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The Levetiracetam and Na-valproate tablets are located in two containers A and B, and the people eligible for inclusion are not aware of the used drug, and the drug was given to patients based on a randomized number table.

## Placebo

Not used

## Assignment

Parallel

## Other design features

.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical Sciences

##### Street address

Babol University of Medical Sciences, Ganj Afrooz

Avenue, Babol, Mazandaran

## City

Babol

## Province

Mazandaran

## Postal code

47176-47745

## Approval date

2018-12-22, 1397/10/01

## Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.195

## Health conditions studied

### 1

#### Description of health condition studied

Epilepsy

#### ICD-10 code

G40.4

#### ICD-10 code description

Lennox-Gastaut syndrome

## Primary outcomes

### 1

#### Description

Recurrence of seizure

#### Timepoint

Every 6 months for one year

#### Method of measurement

Using EEG

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Orally levetiracetam with a dose of 250-500 milligram (mg) for 3 to 6 months

#### Category

Treatment - Drugs

### 2

#### Description

Orally sodium valproate with a dose of 200-500 mg for 3 to 6 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Children's Hospital of Amirkola Babol

**Full name of responsible person**

Dr. Mohammad Reza Salehiomran

**Street address**

Dar ul Shafa Arghavan, Imam Khomeini Arghavan (RA), Amirkola, Babol, Mazandaran

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salehiomran@yahoo.com

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Reza Ghadimi

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Babol University of Medical Sciences, Ganj Afrooz Avenue, Babol, Mazandaran

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Salehiomran

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Faezeh Bolboli

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Pediatrics

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD****Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available