Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3234 2152

Email

salehiomran@yahoo.com

Web page address

http://www.mubabol.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 9592

Email

Rezaghadimi@yahoo.com

Web page address

http://www.mubabol.ac.ir/

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

Street address

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

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Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3234 2152

Email

salehiomran@yahoo.com

Web page address

http://www.mubabol.ac.ir/

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

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 9592

Email

faezeh.bolboli@gmail.com

Web page address

http://www.mubabol.ac.ir/

Person responsible for updating data

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
Street address
Dar ul Shafa Avenue, Imam Khomeini Avenue (RA), Amirkola, Babol, Mazandaran
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 981132342152
Email
salehiomran@yahoo.com
Web page address
http://www.mubabol.ac.ir/

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