

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Clinical trial of evaluation of effectiveness and clinical side effects of levetiracetam and topiramate in control of seizures of oral prednisolone refractory infantile spasms

Protocol summary

Study aim

This study will be done to answer this question that whether or not levetiracetam is more efficient than topiramate in control of seizures of oral prednisolone refractory infantile spasms.

Design

single blinded parallel group clinical trial

Settings and conduct

The drugs will be continued for three months and the children will be followed up monthly for three consecutive months. The trial uses computer generated equal simple randomization by random numbers and data collectors, outcome assessors and data analysts are kept blinded to the allocation.

Participants/Inclusion and exclusion criteria

sixty 2 months-1 year old infants with infantile spasms who would be referred to Pediatric Neurology Clinic of Shahid Sadoughi Hospital, Yazd, Iran that their seizures not controlled with 2 mg/kg/day oral prednisolone for one month, will be distributed randomly into two groups.

Intervention groups

In both groups to minimize side effects of drug, the dose will be increased in a weekly fashion to reach the maximum dose or the dose which controlled seizures in a four week period. In group I, levetiracetam will be started as a minimum of two divided doses and as follows: 10, 20, 30, 40 mg/kg/day. In group II, Topiramate will be started as a minimum of two divided doses and as follows: 3, 5, 7, 9 mg/kg/day. The drugs will be continued for three months and the children will be followed up monthly for three consecutive months.

Main outcome variables

Primary outcomes include daily frequency of seizure and treatment response that will be compared before and after three months of treatment. Secondary outcomes include more than 50% of reduction in daily frequency of seizure and clinical side effects.

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20091027002639N21**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-25, 1397/06/03

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of evaluation of effectiveness and clinical side effects of levetiracetam and topiramate in control of seizures of oral prednisolone refractory infantile spasms

Public title
Effect of levetiracetam and topiramate in infantile spasms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range of 2 months-1 year Having infantile spasms based on definition of the International League Against Epilepsy Resistance of their seizure to treatment of 2 mg/kg/day prednisolone for two months Not used of other antiepileptic drugs
Exclusion criteria:
 Discontinuation of levetiracetam and topiramate usage for more than one week Allergy to levetiracetam and topiramate Irregular drugs usage Not returning for follow up

Age
From **2 months** old to **1 year** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **60**
 More than 1 sample in each individual
 Number of samples in each individual: **30**
 sixty 2 months-1 year old infants with infantile spasms who would be referred to Pediatric Neurology Clinic of Shahid Sadoughi Hospital, Yazd, Iran that their seizures not controlled with 2 mg/kg/day oral prednisolone for one month , will be distributed randomly into two groups'

Randomization (investigator's opinion)
Randomized

Randomization description
Computer generated equal simple randomization by random numbers

Blinding (investigator's opinion)
Single blinded

Blinding description
Data collectors, outcome assessors and data analysts are kept blinded to the allocation.

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Street address

Central building of university, Bahonar square

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2018-08-25, 1397/06/03

Ethics committee reference number

IR.SSU.MEDICINE.REC.1397.085

Health conditions studied

1

Description of health condition studied

Infantile spasms

ICD-10 code

G40.4

ICD-10 code description

Other generalized epilepsy and epileptic syndromes

Primary outcomes

1

Description

Daily frequency of seizure

Timepoint

Before and after three months of treatment

Method of measurement

Asking from patient parents

2

Description

Treatment response

Timepoint

Before and after three months of treatment

Method of measurement

Asking from patient parents

Secondary outcomes

1

Description

Frequency of more than 50 % of reduction in daily

frequency of seizure
Timepoint
Before and three months after treatment
Method of measurement
Asking from parents of patient

2

Description
Clinical side effects
Timepoint
During three months of treatment
Method of measurement
Asking from parents of patient

Intervention groups

1

Description
Intervention group1: Topiramate tablet of 25 or 50 mg from Darou Paksh Co, Iran with dosage of 3-9mg/kg/day divided into two doses for three months
Category
Treatment - Drugs

2

Description
Intervention group2: Levebel syrup of 120 cc from Cobel Darou Co, Iran each milliliter contains 100 mg of levatiracetam per with dosage of 10- 40mg/kg/day divided into two doses for three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Neurology Clinic of Shahid Sadoughi University of Medical Sciences, Yazd, Iran
Full name of responsible person
Professor Razieh Fallah
Street address
Shahid Sadoughi Hospital, Ebnsina Blvd, Shahid Ghandi Blvd
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dr.raziehfallah@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mahmood Vakili
Street address
Central building of university, Bahonar Square
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vakilim52@ssu.ac.ir
Web page address
Grant name
No
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr.Nahid Zareeian
Position
Resident of Pediatrics
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available