

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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, Ebsina Blvd, Shahid Ghandi Blvd

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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

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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

Name of organization / entity
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Professor Razieh Fallah
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
pediatric neurology
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Person responsible for updating data

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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