Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 levatiracetam 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
،he 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, levatiracetam 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

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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 Pakhsh 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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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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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Professor Razieh Fallah
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Professor
Latest degree
Subspecialist
Other areas of specialty/work
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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