Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of Topiramate and Amitriptyline Prophylactic therapy on cyclic vomiting syndrome in Pediatrics

Protocol summary

Summary

Our goal is to evaluate the efficacy of topiramate and amitriptyline administration in patients with cyclic vomiting syndrome (CVS) and compare the results with each other. For this purpose, we will enroll 60 patents with CVS in the study and divide them into two groups of topiramate and amytriptiline. Patients need to be children 3-15 years old, with diagnosis of cyclic vomiting syndrome based on Rome III criteria. Normal neurological and developmental examination are needed and patients with known metabolic disease and obstructive disease of gastrointestinal or urinary system will be excluded from the study. The study is designed single blinded and patients don't know about their medication. This is a 2-3 phase trial and is run in one center only. Patients will be followed for three month and will be observed closely for their episodes of the disease. At the end, we will compare the severity of cyclic vomiting syndrome symptoms as the primary outcome, between groups, to find the more effective treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102316844N2**
Registration date: **2016-02-27, 1394/12/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-27, 1394/12/08

Registrant information

Name

Shervin Badihian

Name of organization / entity

Isfahan University of Medical Sicences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Isfahan University of Medical Sciences

Expected recruitment start date

2016-02-14, 1394/11/25

Expected recruitment end date

2016-04-13, 1395/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Topiramate and Amitriptyline Prophylactic therapy on cyclic vomiting syndrome in Pediatrics

Public title

Which one is more effective in cyclic vomiting syndrome treatment? Topitamate or Amitriptyline ?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children 3-15 years old with diagnosis of cyclic vomiting syndrome (based on Rome III criteria: 1 Stereotypical episodes of vomiting regarding onset (acute) and duration (less than 1 week); 2) Three or more discrete episodes in the prior year; and 3) Absence of nausea and vomiting between episodes and absence

of metabolic, gastrointestinal, central nervous system structural or biochemical disorders); Normal Neurological and Developmental examination Exclusion criteria: Known metabolic disease; Obstructive disease of gastrointestinal or urinary system; Patients who don't give consent to participate in the study or want to leave the study anytime.

Age
From **3 years** old to **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization is performed using table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib St.

City
Isfahan

Postal code
8174673461

Approval date
2013-12-02, 1392/09/11

Ethics committee reference number
393229

Health conditions studied

1

Description of health condition studied
Cyclical vomiting syndrome

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Severity of cyclic vomiting syndrome

Timepoint
for 3 months after starting the medication. Patients are followed every two weeks after starting the medication

Method of measurement
questionnaire (evaluating number of attacks and duration of attacks)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In one group we will start topiramate for patients with the dosage of 1-2 mg/kg daily. Patients won't be aware of their drugs. The medication will be used for at list three months during the study. The medication is produced by Pars Daru company in Iran.

Category
Treatment - Drugs

2

Description
Control group: In the other group we will start Amitriptyline for patients with the dosage of 1 mg/kg daily. The medication will be used for at list three months during the study. The medication is produced by Pars Daru company in Iran.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Mousa Sadr Clinic

Full name of responsible person
Zahra Bagherian

Street address
Foroughi St.

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mahdi Nematbakhsh

Street address

Hezar Jarib St.

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Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences, Child Growth and Development Research Center

Full name of responsible person

Zahra Bagherian

Position

Pediatric resident/M.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences, child Growth and Development Research Center

Full name of responsible person

Omid Yaghini

Position

Member of Faculty of Medicine/ MD, Pediatrician

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences, School of Medicine, Students' Research Center

Full name of responsible person

Shervin Badihian

Position

Medical Student

Other areas of specialty/work

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Phone

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Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty