

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

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

Protocol summary

2015-10-20, 1394/07/28

Summary

Our goal is to evaluate the efficacy of cyproheptadine and amitriptyline administration in patients with cyclic vomiting syndrome (CVS) and compare the results with each other. It is worthy to note that other drugs are also suggested before as the treatment for CVS, however amytriptiline and cyproheptadine are among the drugs with more supporting evidence on this subject. For this purpose, we will enroll 60 patents with CVS in the study and divide them into two groups of cyproheptadine 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 six months 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. Results of this study may help physicians to prescribe the appropriate drug for their patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030416844N1**

Registration date: **2015-10-20, 1394/07/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Shervin Badihian

Name of organization / entity

Isfahan University of Medical Scinces

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research of Isfahan University of Medical Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2015-12-30, 1394/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Which one is more effective in cyclic vomiting syndrome treatment? Cyproheptadine 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**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

2014-04-21, 1393/02/01

Ethics committee reference number

292210

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

From the recruitment date to 6 months after starting the medication. Patients are followed every two weeks after starting the medication.

Method of measurement

questionnaire (evaluating number of attacks, duration of attacks, number of hospitalization)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In one group we will start Amitriptyline for patients with the dosage of 1 mg/kg daily. Patients won't be aware of their drugs.

Category

Treatment - Drugs

2**Description**

Control group: In the other group we will start Cyptoheptadine for patients with the dosage of 0.1-0.2 mg/kg BID.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Mousa Sadr Clinic

Full name of responsible person

Shervin Badihian

Street address

Foroughi St.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mahdi Nematbakhsh

Street address

Hezar Jarib St.

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor of 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, School of Medicine, Students' Research Center

Full name of responsible person

Shervin Badihian

Position

Medical Student

Other areas of specialty/work**Street address**

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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

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Member of Faculty of Medicine/ MD, Pediatrician

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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