Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of propranolol alone and propranolol with L-carnitine in the prophylactic treatment of cyclic vomiting syndrome in children

Protocol summary

Study aim
Determining the effect of propranolol alone in comparison with propranolol with L-carnitine in the prophylactic treatment of cyclic vomiting syndrome in children

Design
A clinical trial, with the parallel groups, single-blinding, randomized

Settings and conduct
This randomized single-blind clinical trial study is performed in the pediatric gastrointestinal clinic of Imam Hossein Hospital. In this study, 104 children with cyclic vomiting syndrome will be included and randomly divided into 2 parallel groups. One group receives propranolol alone and the other group receives propranolol with L-carnitine tablets daily. The incidence of vomiting attacks, its severity and intervals before and during 6 months after the start of treatment will be recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children 3 to 18 years old with cyclic vomiting syndrome who have more than two seizures in a month. Also no seizures, metabolic diseases, and gastrointestinal diseases.

Intervention groups
Intervention group 1: Patients receive propranolol tablets(Poursina Pharmaceutical Co.) at a dose of 1 mg/kg daily with L-carnitine tablets(Poursina Pharmaceutical Co.) at a dose of 50-100 mg/kg with a maximum dose of 2 g daily for three months.
Intervention group 2: Patients receive only propranolol tablets(Poursina Pharmaceutical Co.) at a dose of 1 mg/kg daily for three months.

Main outcome variables
Incidence of vomiting attacks; Severity of vomiting attacks

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120716010297N9**
Registration date: **2020-08-17, 1399/05/27**
Registration timing: **prospective**

Last update: **2020-08-17, 1399/05/27**
Update count: **0**

Registration date
2020-08-17, 1399/05/27

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2021-04-21, 1400/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of propranolol alone and propranolol with L-carnitine in the prophylactic treatment of cyclic vomiting syndrome in children

Public title
The role of propranolol with L-carnitine in the prophylactic treatment of cyclic vomiting syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
cyclic vomiting syndrome with more than two attacks in a month No seizures No metabolic diseases No gastrointestinal diseases

Exclusion criteria:

Age
From **3 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
First, eligible patients will be simple randomly selected. Then they will be divided into two groups of 52 using the random block method with 2 blocks. So that the first two cases are separated and assigned to group one, the second two cases are separated and assigned to group two, and this will be continued two by two in the same way till the ending of samples.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the different dosage of the drugs and the combination of the two drugs in one of the two groups, it is not possible for the researcher to be blind and the child's parents will be aware. But a statistician of the two groups will not know.

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
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

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Province
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Postal code
8179964167

Approval date
2019-12-22, 1398/10/01

Ethics committee reference number
IR.MUI.MED.REC.1398.461

Health conditions studied

1

Description of health condition studied
Cyclic vomiting syndrome

ICD-10 code
G43.A0

ICD-10 code description
Cyclical vomiting

Primary outcomes

1

Description
Incidence of vomiting attacks

Timepoint
Before and during 6 months after the start of the intervention

Method of measurement
Observation

2

Description
Severity of vomiting attacks

Timepoint
Before and during 6 months after the start of the intervention

Method of measurement
Visual scale(Score 1 lowest severity and score 10 highest severity of vomiting attacks)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients receive propranolol tablets (Poursina Pharmaceutical Co.) at a dose of 1 mg/kg daily

with L-carnitine tablets (Poursina Pharmaceutical Co.) at a dose of 50-100 mg/kg with a maximum dose of 2 g daily for three months.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients receive only propranolol (Poursina Pharmaceutical Co.) at a dose of 1 mg/kg daily for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Gastroenterology Clinic of Imam Hossein Hospital

Full name of responsible person

Somayeh Janani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Famouri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available