

# 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

##### Name

Leili Allahbakhshian

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1668 7079

##### Email address

allahbakhshian@med.mui.ac.ir

##### 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

### City

Isfahan

### Province

Isfahan

### 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

**Street address**

Imam Khomeini Street, Isfahan.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8195163381

**Phone**

+98 31 3386 6266

**Email**

emamhossein\_hospital@mui.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo Javanmard

**Street address**

Vice Chancellor for Research and Technology,  
Building No. 4, Isfahan University of Medical Sciences,  
Hezar Jarib Street, Isfahan.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Fax****Email**

research@mui.ac.ir

**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**

Pediatrics

**Street address**

Unit 4, Parisa apartment, Alley 5, Mehrabad Street,  
Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 0048

**Email**

fat.famoori@gmail.com

**Person responsible for scientific 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**

Pediatrics

**Street address**

Unit 4, Parisa apartment, Alley 5, Mehrabad Street,

Isfahan.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
7346181746  
**Phone**  
+98 31 3668 0048  
**Email**  
fat.famoori@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Somayeh Janani  
**Position**  
resident  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
No. 17, Shahid Mahmoudi Alley, Bozorgmehr Street,  
Isfahan.

**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
7346124611  
**Phone**  
+98 31 3668 0048  
**Email**  
somayeh\_janani1361@yahoo.com

## 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