

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the Effectiveness of L-Carnitin and Propranolol in Prophylaxis of Headache Attacks in Migrainous Children

#### Protocol summary

##### Study aim

Find A New Drug Method to Prevent Migraine Headaches

##### Design

Clinical trial without control, with parallel groups, randomized

##### Settings and conduct

In this study, children with migraine who referred to Imam Hossein and Amin hospitals in Isfahan university of science are evaluated. The participants are randomly divided in to two groups. The first group is treated with 50 mg/kg L-carnitine daily. The second group is treated with 1 mg/kg Propranolol daily. The headache severity, headache frequency and headache duration are compared between two groups 2 weeks, 1 month and 3 months after beginning of treatment.

##### Participants/Inclusion and exclusion criteria

Children with migraine whose disease has recently been diagnosed according to the International Headache Society (IHS) criteria, are currently under no preventive treatment and have at least a weekly migraine headache; Patients who have more than four headache attacks in a month (severe migraine forms) are not included in the study.

##### Intervention groups

In this study, participants are divided in to two groups. The first group is treated with 50 mg/kg L-Carnitine once a day. The second group is treated with 1 mg/kg Propranolol once a day. Then. headache duration, headache severity and headache frequency are compared between two groups.

##### Main outcome variables

Headache severity, headache duration, headache frequency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190128042533N1**

Registration date: **2019-03-02, 1397/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-02, 1397/12/11**

Update count: **0**

##### Registration date

2019-03-02, 1397/12/11

##### Registrant information

###### Name

Omid Yaghini

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3234 1294

###### Email address

yaghini@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-22, 1397/11/02

##### Expected recruitment end date

2019-04-22, 1398/02/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effectiveness of L-Carnitin and Propranolol in Prophylaxis of Headache Attacks in Migrainous Children

##### Public title

The Effect of L-Carnitin in Treatment of Migraine

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Children with migraine whose disease has recently been diagnosed with the International Headache Society (IHS) criteria. Not currently under any preventive treatment. Have a migraine headache for at least once a week.

### Exclusion criteria:

Patients who have more than four headache attacks in a month (severe migraines)

## Age

From **5 years** old to **15 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **88**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not 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 Science

##### Street address

Isfahan University of Medical Science, Hezarjrib Stret, Isfahan City

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2017-09-21, 1396/06/30

#### Ethics committee reference number

IR.MUI.MED.REC.1397.245

## Health conditions studied

### 1

#### Description of health condition studied

Migraine

#### ICD-10 code

G43

#### ICD-10 code description

Migraine

## Primary outcomes

### 1

#### Description

Headache severity

#### Timepoint

Two weeks, one month, three months after beginning of treatment

#### Method of measurement

Pediatric Migraine Disability Assessment Scale

### 2

#### Description

Headache frequency

#### Timepoint

Two weeks, one month, three months after beginning of treatment

#### Method of measurement

interview

### 3

#### Description

Headache duration

#### Timepoint

Two weeks, one month, three months after beginning of treatment

#### Method of measurement

Interview

## Secondary outcomes

### 1

#### Description

Medication side effects

#### Timepoint

Two weeks, one month, three months after beginning of treatment

#### Method of measurement

Physical examination

## Intervention groups

### 1

#### Description

Intervention group: In this group, patients are treated with 50 mg/kg L-carnitine daily.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: In this group, patients are treated with 1 mg/kg Propranolol daily.

**Category**

Treatment - Drugs

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

Imam Hossein Hospital

**Full name of responsible person**

Omid Yaghini

**Street address**

Imam Hossein Hospital, Imam Khomeini street,  
Isfahan City

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8195163381

**Phone**

+98 31 3386 6266

**Email**

Yaghini@med.mui.ac.ir

**2****Recruitment center****Name of recruitment center**

Amin Hospital

**Full name of responsible person**

Omid Yaghini

**Street address**

Amin Hospital, Ebne Sina Street, Isfahan City

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8148653141

**Phone**

+98 31 3445 5051

**Email**

Yaghini@med.mui.ac.ir

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjou javanmard

**Street address**

Isfahan University of Medical Science, Hezarjrib  
Street, Isfahan City

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

Sh\_haghjoo@med.mui.ac.ir

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

Yes

**Title of funding source**

Esfahan 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**

Laya Amini

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

No. 11, 1 alley, Emam Jafar Sadegh alley, Hezarjarib  
Ave., Isfahan City

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174663771

**Phone**

+98 31 3673 6515

**Email**

layaamini66@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Omid Yaghini

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Imam Hossein Hospital, Imam Khomeini Street,  
Isfahan City

**City**

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**Province**

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8195163381

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**Email**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Laya Amini

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Email**

layaamini66@yahoo.com

## 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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable