

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

Amin Hospital

Full name of responsible person

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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?**

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Omid Yaghini

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

Pediatrics

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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