Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Isfehan

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 begining of treatment

Method of measurement

Pediatric Migraine Disability Assessment Scale

2

Description

Headache frequency

Timepoint

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

Method of measurement

interview

3

Description

Headache duration

Timepoint

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

Method of measurement

Interview

Secondary outcomes

1

Description

Medication side effects

Timepoint

Two weeks, one month, three months after begining 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
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8195163381
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2

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
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Amin Hospital, Ebne Sina Street, Isfahan City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjou javanmard
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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
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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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
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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