

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

A comparative study of the efficacy of coenzyme Q10 and amitriptyline in the prophylactic treatment of migraine headaches in children; An open-label randomized controlled trial

Protocol summary

Study aim

Evaluation and comparison of the efficacy of Q10 and amitriptyline in the prevention of childhood migraine headaches

Design

A randomized, open-labeled clinical trial with 2 parallel groups, design of 72 patients, enrolled from August 2019, and followed for 4 months

Settings and conduct

This study include children referred to pediatric neurology clinic in Imam Hosein children hospital, Isfahan. Only, data analyzers remains blind in this survey.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Children 5 to 15 year old with migraine with or without aura referred to a clinic of neurology and disease is diagnosed definitively on the basis of IHS 2) Migraine attacks occur at least twice a week or four times a month, forcing them to consume or disrupt their daily activities Exclusion criteria: 1) Patients' unwillingness to cooperate during the study 2) Severe and uncontrolled side effects of Q10 or Amitriptyline 3) If a diagnosis other than migraine is made during the study, based on possible laboratory or imaging findings. 4) Complicated migraine or epilepsy 5) Lack of ability to record data on the frequency, duration, and severity of headaches 6) Taking prophylaxis other than Q10 and amitriptyline 7) Children with migraines with severe psychiatric problems such as ADHD and depression 8) Using painkillers more than 4 times a week to control migraine attacks (severe forms of migraines) 9) A history of allergy to similar drugs used

Intervention groups

In this study, participants are divided into groups A and B, group A is treated with Q10 and group B is treated with Amitriptyline. Patients are followed up for three months for the frequency, duration, and severity of

migraine attacks and drug side effects.

Main outcome variables

Headaches frequency; Headaches duration, Headaches severity, Patients quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190208042654N2**

Registration date: **2020-01-05, 1398/10/15**

Registration timing: **retrospective**

Last update: **2020-01-05, 1398/10/15**

Update count: **0**

Registration date

2020-01-05, 1398/10/15

Registrant information

Name

Vahid Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 3653

Email address

v.mansoury@edc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

2019-08-06, 1398/05/15
Actual recruitment end date

2019-12-06, 1398/09/15
Trial completion date
2019-12-06, 1398/09/15

Scientific title

A comparative study of the efficacy of coenzyme Q10 and amitriptyline in the prophylactic treatment of migraine headaches in children; An open-label randomized controlled trial

Public title

A comparative study on the efficacy of coenzyme Q10 and amitriptyline in the prophylactic treatment of migraine headaches in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children with migraine with or without aura referred to a clinic of neurology and disease is diagnosed definitively on the basis of IHS. Migraine attacks occur at least twice a week or four times a month, forcing them to consume or disrupt their daily activities. Children 5 to 15 year old

Exclusion criteria:

Patients' unwillingness to cooperate during the study. Severe and uncontrolled side effects of Q10 or Amitriptyline If a diagnosis other than migraine is made during the study, based on possible laboratory or imaging findings Complicated migraine or epilepsy Lack of ability to record data on the frequency, duration, and severity of headaches Taking prophylaxis other than Q10 and amitriptyline Children with migraines with severe psychiatric problems such as ADHD and depression Using painkillers more than 4 times a week to control migraine attacks (severe forms of migraines) A history of allergy to similar drugs

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial, which begins in summer 2019, 72 participants are selected from the patients referred to the neurology department of Imam Hossein Hospital in a non-randomized and simple method, if they met the inclusion criteria. Adequate explanations will be given to parents and informed consents will be obtained. Patients were randomly assigned using SPSS generated random numbers and binary blocks to either A or B groups (Coenzyme Q10 or Amitriptyline) at the time of

administering treatment. In this study, participants will be divided into two groups after allocation of code to each patient and then randomly dividing the codes between two groups and the person in charge is blind to participants.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, physicians and patients will aware of study groups and only, statistical analyser will be blind for treatment groups. Each group will be assigned with A or B, making the analyser blind for the treatment groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of medical science

Street address

Hezar jarib Ave

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2019-08-05, 1398/05/14

Ethics committee reference number

IR.MUI.MED.REC.1398.239

Health conditions studied

1

Description of health condition studied

Migraine headaches

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Comparison of the effect of Q10 and amitriptyline on the prophylaxis of migraine headaches

Timepoint

Before intervention, 1,2 and 3 months after intervention

Method of measurement

PedMIDAS quality of life checklist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group 1: Coenzyme Q10 is available in the form of 100 mg coated tablets, 30 and 100 mg capsules and 100 mg soft gel. In this study, the dose used is Q10 for children less than 30 kg 30 mg and for children over 30 kg 60 mg and from Eurovital Pharmaceutical Company.

Category

Prevention

2**Description**

Intervention group: Intervention group 2: Amitriptyline 25 mg tablet of Daroupakhsh industry is available for children. if the dose is greater than 1 -2 mg/kg it will be divided at noon and bedtime.

Category

Prevention

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

Imam Hosein Hospital

Full name of responsible person

Neda Hoseini

Street address

Imam Khomeini Ave

City

Isfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 8247

Email

neda.8892@yahoo.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Hezar jarib Ave

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

sh_haghjoo@med.mui.ac.ir

Grant name**Grant code / Reference number**

398286

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

Omid Yaghini

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Imam Khomeini street

City

Isfahan

Province

Isfahan

Postal code

81951-63381

Phone

+98 31 3234 6022

Email

yaghini@med.mui.ac.ir

Person responsible for scientific inquiries**Contact**

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Omid Yaghini
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Imam Khomeini street
City
Isfahan
Province
Isfahan
Postal code
81951-63381
Phone
+98 31 3234 6022
Email
yaghini@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Omid Yaghini
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics

Street address
Imam Khomeini street
City
Isfahan
Province
Isfahan
Postal code
81951-63381
Phone
+98 31 3234 6022
Email
yaghini@med.mui.ac.ir

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

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

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

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

Data Dictionary

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