Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 fallowed 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

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Name of organization / entity

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Iran (Islamic Republic of)

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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

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Province

Isfehan

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
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Sponsors / Funding sources

1

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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
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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
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