

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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

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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 analyster

**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

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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

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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****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

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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**

assistant professor

**Latest degree**

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**Other areas of specialty/work**

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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

**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