Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of combined supplementation Coenzyme Q10 with L-carnitine on mitochondrial metabolic disorders markers and migraine symptoms among patient with migraine by following a tyramine-controlled diet.

Protocol summary

Study aim

Evaluation the impact of combined supplementation Coenzyme Q10 with L-carnitine on mitochondrial metabolic disorders markers and migraine symptoms among patient with migraine

Design

we will enroll 56 eligible patients with migraine aged 20-49 years that will be recruited from Imam Mousa Sadr Clinic will randomly assigned into treatment and placebo groups.

Settings and conduct

The present study is a double-blind randomized clinical trial study and participants, researcher, and statistical analyser will not know from assigned intervention. The population includes 56 patients with migraine that will be recruited from Imam Mousa Sadr Clinic. The participants will randomly assigned into treatment and placebo groups to receive Coenzyme Q10 with L-carnitine or placebo tablets for 8 weeks. migraine symptoms, depression and biochemical assessment will be measured at the beginning and end of each phases.

Participants/Inclusion and exclusion criteria

patients with migraine (with or without aura), both sex, nonpregnant, nonlactative, nonsmokers, non-alcoholic and willing to participate in the study/contain history of chronic diseases, chronic tension-type headache or secondary headaches.

Intervention groups

The treatment group will receive 30 mg/day Coenzyme Q10 with 250 mg/day L-carnitine at the same time for 8-weeks and subject in the other group also will receive the placebo tablets. Individuals in both group will receive a list of tyramine contains foods and will be asked not to consume any of these foods during the study.

Main outcome variables

Migraine symptoms (severity , frequency and average duration of migraine attacks), Serum Lactate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N21**
Registration date: **2017-12-03, 1396/09/12**
Registration timing: **retrospective**

Last update: **2017-12-03, 1396/09/12**
Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of combined supplementation Coenzyme Q10 with L-carnitine on mitochondrial metabolic disorders markers and migraine symptoms among patient with migraine by following a tyramine-controlled diet.

Public title
Effect of combined supplementation Coenzyme Q10 with L-carnitine on migraine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with migraine (with or without aura) both sex nonpregnant nonlactative nonsmokers non-alcoholic willing to participate in the study

Exclusion criteria:
contain history of chronic diseases chronic tension-type headache or secondary headaches medication or supplements use following a diet program during the past 6 month following exercise program during the past 6 month

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
In present study, simple randomization method will be used. The randomization unit is individually and we will use the random number table method for random sequences. A random numbered table is a collection of numbers that are without a specific pattern, completely random and as table. The next step is allocation concealment and will use sequentially numbered, sealed, opaque envelopes. Then, based on the sample size, number of envelopes with aluminum surface are provided and each random sequence created on a card and the cards are inserted into the envelopes, respectively. At the time of registration for the participants, according to eligible participants, one of the envelopes is opened and the allocated group for participants is revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is a double blind method and participants, researcher, and statistical analyser will not know according to assigned intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue

City
Isfahan

Province
Isfehan

Postal code
8135798111

Approval date
2017-05-01, 1396/02/11

Ethics committee reference number
IR.MUI.REC.1396.3.054

Health conditions studied

1

Description of health condition studied
migraine

ICD-10 code
G43.9

ICD-10 code description
Migraine, unspecified

Primary outcomes

1

Description
Migraine symptoms (severity , frequency and average duration of migraine attacks)

Timepoint
week 0 and week 8

Method of measurement
Questionaire

2

Description
Serum Lactate

Timepoint
week 0 and week 8

Method of measurement

Laboratory analysis (blood test)

Secondary outcomes

1

Description
Migraine Disability Assessment
Timepoint
week 0 and week 8
Method of measurement
Questinaire

2

Description
Depression
Timepoint
week 0 and week 8
Method of measurement
Questinaire

Intervention groups

1

Description
Intervention group: 30 mg/day Coenzyme Q10 with 250 mg/day L-carnitine at the same time for 8- weeks control group: placebo tablets for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Mousa Sadr Clinic
Full name of responsible person
Parisa Hashemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
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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