

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Sep 2026

Effect of oral Co-Q10 supplementation on nutrition status, migraine attacks, inflammatory biomarkers, oxidative stress and CGRP neuropeptide in women with migraine

Protocol summary

Summary

The aim of the current study is to determine the effect of oral Co-Q10 supplementation on nutrition status, migraine attacks, inflammatory biomarkers, oxidative stress and CGRP neuropeptide in women with migraine. Eighty four female patients with aged 18-50 years old suffering from migraine based on ICH criteria with the history of at least two episodic migraine (with or without aura) attacks per month for more than one year will be studied in a double blind randomized control clinical trial . Patients will be randomized to one of the Co-Q10 or placebo groups. Intervention duration will be three months (after a month for run-in period) and intervention group will receive 400 mg/day Co-Q10 as 2 capsules of 200 mg besides their usual anti-migraine treatments and control group will receive placebo capsules besides their usual anti-migraine drugs. Nutritional status, migraine attacks (frequency, severity and duration) with valid specific migraines questionnaires , anthropometric indexes and physical activity levels at the base, middle and at the end of the study and also inflammatory factors(TNF- α , IL-10 and IL-6), Oxidative factors (MDA, TAC), CGRP neuropeptide, lipid profile(TG, HDL-C, LDL-C and TC) and serum Co-Q10 level at the base and the end of the study will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508265670N10**
Registration date: **2015-12-29, 1394/10/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-29, 1394/10/08

Registrant information

Name

Ali Tarighat-Esfanjeni

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 914 300 5895

Email address

tarighata@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences - Nutrition Research Center

Expected recruitment start date

2015-12-21, 1394/09/30

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral Co-Q10 supplementation on nutrition status, migraine attacks, inflammatory biomarkers, oxidative stress and CGRP neuropeptide in women with migraine

Public title

Effect of Co-Q10 in migraine

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: Female; patient tendency and ability to participate in the study; age between 18-50; a definitive diagnosis of migraine based on IHS criteria; headache history for at least one year; episodic migraine with or without aura; having at least two headaches per month. Exclusion criteria: Menopause; suffering from tension type or other headaches; having chronic disease (such as diabetes, cardiovascular disease, chronic kidney disorders and functional liver disorders and cancers); having history of stroke or MI; smoking; pregnancy or intend to pregnancy or lactation; using CO-Q10 during the last three month before study; daily or almost daily using(>15/month) of narcotics; using antioxidant supplements; consuming anti-hypertention and anti-hyperlipidemia drugs.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Postal code

Approval date

2015-12-07, 1394/09/16

Ethics committee reference number

TBZMED.REC.1394.835

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0, G43

ICD-10 code description

Migraine without aura [common migraine], Migraine with aura [classical migraine]

Primary outcomes

1

Description

migraine frequency

Timepoint

at the baseline, 6 and 12 weeks after the intervention

Method of measurement

questionnaire

2

Description

migraine severity

Timepoint

at the baseline, 6 and 12 weeks after the intervention

Method of measurement

questionnaire

3

Description

migraine duration

Timepoint

at the baseline, 6 and 12 weeks after the intervention

Method of measurement

questionnaire

4

Description

CGRP Neuropeptide

Timepoint

at the baseline and 12 weeks after the intervention

Method of measurement

ELISA kit

5

Description

TNF-a

Timepoint

at the baseline and 12 weeks after the intervention

Method of measurement

ELISA kit

6

Description

IN-6

Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
ELISA kit

7

Description
IL-10
Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
ELISA kit

8

Description
TAC
Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
spectrophotometry

9

Description
MDA
Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
TBA (Thio Barbituric Acid)

10

Description
triglyceride(TG)
Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
enzymatic method

11

Description
total cholesterol (TC)
Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
anzymatic method

12

Description
high density lipoprotein cholesterol (HDL-c)
Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
anzymatic method

13

Description
low density lipoprotein cholesterol (LDL-c)
Timepoint

at the baseline and 12 weeks after the intervention

Method of measurement
Friedewald Equation

14

Description
serum Co-Q10 levels
Timepoint
at the baseline and 12 weeks after the intervention
Method of measurement
HPLC

15

Description
dietary intake
Timepoint
at the baseline, 6 and 12 weeks after the intervention
Method of measurement
3 days food record

16

Description
anthropometric measurements
Timepoint
at the baseline, 6 and 12 weeks after the intervention
Method of measurement
BMI, waist circumference and body fat percent

17

Description
Added at 2017-02-08: pyruvate
Timepoint
Added at 2017-02-08: at the baseline and 12 weeks after the intervention
Method of measurement
Added at 2017-02-08: ELISA kit

18

Description
Added at 2017-02-08: Nitric oxide
Timepoint
Added at 2017-02-08: at the baseline and 12 weeks after the intervention
Method of measurement
Added at 2017-02-08: Elisa kit

19

Description
Added at 2017-02-08: Lactate
Timepoint
Added at 2017-02-08: at the baseline and 12 weeks after the intervention
Method of measurement
Added at 2017-02-08: Elisa Kit

20

Description

Added at 2017-02-08: Matrix metalloproteinases9

Timepoint

Added at 2017-02-08: at the baseline and 12 weeks after the intervention

Method of measurement

Added at 2017-02-08: ELISA kit

Secondary outcomes

1

Description

physical activity

Timepoint

at the baseline, 6 and 12 weeks after the intervention

Method of measurement

IPAQ questionnaire

Intervention groups

1

Description

Intervention group will receive daily two 200 mg capsule of Coenzyme Q10 with meal for three months besides their usual treatments

Category

Prevention

2

Description

control group will receive daily two capsule of placebo for three months besides their usual treatments

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golgasht Medical center

Full name of responsible person

Dr.Maziar Hashemilar

Street address

Tabriz,Golgasht st,Golgasht medical center, fourth floor

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of

Medical Sciences - Nutrition Research Center

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Nutrition Faculty, Attarneyshabouri street, Golgasht street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Tabriz University of Medical Sciences - Nutrition Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Ali Tarighat-Esfanjani

Position

Ph.D. of Nutrition

Other areas of specialty/work

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty