

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The combined effects of omega3 fatty acids and curcumin supplementation on Oxidative Stress in migraine patients

Protocol summary

Summary

Present study aimed to examination the effects of supplementation of omega-3, nano-curcumin and combination of them on oxidative stress in patients with migraine. Inclusion criteria included age 20-50, patients with episodic migraine, any other disorders, avoidance of consumption of supplements or vitamins and any use of special diet, supplements or activity. Exclusion criteria comprise of allergic reaction to omega-3 or nano-curcumin compounds, unwilling of patient to cooperation, pregnancy, any sever changes in diet, usual lifestyle, taking drugs or dosage and any inflammatory disorders that patients have to take anti-inflammatory drugs more than 2 weeks. Eighty migraine patients enrolled in this randomized double-blind clinical trial study and allocated to 4 groups based on stratified randomization method including: 1) receiving combination of omega-3 and nano-curcumin 2) receiving omega-3 and placebo of nano-curcumin 3) receiving nano-curcumin and placebo of omega-3 and 4) receiving omega-3 placebo and nano-curcumin placebo. Patients in omega-3 group take 2 capsules of 1250 mg twice/day, in nano-curcumin group the patients take one capsule of 80 mg nao-curcumin once/day and the combined group take both of them. Control group also take placebo. At the beginning and the end of the study, serum levels of malondialdehyde, glutathione peroxidase and superoxide dismutase will be evaluated by ELISA method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015073123434N1**

Registration date: **2017-07-23, 1396/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-23, 1396/05/01

Registrant information

Name

Mina Abdolahi

Name of organization / entity

School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

m-abdolahi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The combined effects of omega3 fatty acids and curcumin supplementation on Oxidative Stress in migraine patients

Public title

The effects of Omega-3 and nano-curcumin on migraine disorder

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 20-50; patients with episodic migraine; any other disorders; avoidance of consumption of supplements or vitamins at least 4-6 weeks before intervention and during study; any use of special diet, supplements of activity. Exclusion criteria: Allergic reaction to omega-3 or nano-curcumin compounds; Cancel of patient from cooperation; pregnancy; any sever changes in diet, usual lifestyle or taking drugs; any inflammatory disorders that have to take anti-inflammatory drugs (more than 2 weeks).

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Poursina St, Boulvar Keshavarz

City

Tehran

Postal code

Approval date

2017-04-26, 1396/02/06

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2138

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

serum levels of Malondialdehyde

Timepoint

before and after 2 months intervention

Method of measurement

ELISA (Pg/ml)

2

Description

serum levels of Glutathione peroxidase

Timepoint

before and after 2 months intervention

Method of measurement

ELISA (Pg/ml)

3

Description

serum levels of Superoxide dismutase

Timepoint

before and after 2 months intervention

Method of measurement

ELISA (Pg/ml)

Secondary outcomes

1

Description

Body Mass Index

Timepoint

befor and after 2 months intervention

Method of measurement

calculating from weight (kg)/height (m2)

2

Description

weight

Timepoint

befor and after 2 months intervention

Method of measurement

Scales (kg)

3

Description

waist circumference

Timepoint

befor and after 2 months intervention

Method of measurement

tape meter (cm)

Intervention groups

1

Description

Group 1: receiving omega-3 fatty acids capsules, 1250 twice per day with lunch, for 2 months and nano-curcumin capsule, 80 mg once per day with dinner for 2 months

Category

Treatment - Drugs

2

Description

Group 2: receiving omega-3 fatty acids capsules, 1250 twice per day with lunch, for 2 months and placebo of nano-curcumin capsule, 80 mg included oral paraffin once per day with dinner for 2 months

Category

Treatment - Drugs

3

Description

Group 3: receiving nano-curcumin capsule, 80 mg once per day with dinner for 2 months and placebo of omega-3 fatty acids capsules, 1250 mg included oral paraffin twice per day with lunch, for 2 months

Category

Treatment - Drugs

4

Description

group 4 (control): receiving placebo of omega-3 fatty acids capsules, 1250 mg included oral paraffin twice per day with lunch, for 2 months and placebo of nano-curcumin capsule, 80 mg included oral paraffin once per day with dinner for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian center of neurological researchers

Full name of responsible person

Dr. Abass Tafakhori

Street address

Imam Khomeini Hospital, Bouvar Keshavarz Terminal

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Full name of responsible person

Ms. Fatemeh Javadi

Street address

No. 44, HojatDost alley, Naderi Street, Bouvar Keshavarz

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

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

Name of organization / entity

Faculty of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mina A bdolahi

Position

Ph.D in Nutrition sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address**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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University Medical of Sciences

Full name of responsible person

Ms. Mina Abdolahi

Position

Ph.D in Nutritional Sciences

Other areas of specialty/work