

# 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**

before and after 2 months intervention

#### **Method of measurement**

calculating from weight (kg)/height (m<sup>2</sup>)

### 2

#### **Description**

weight

#### **Timepoint**

before and after 2 months intervention

#### **Method of measurement**

Scales (kg)

### 3

#### **Description**

waist circumference

#### **Timepoint**

before 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

##### Street address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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

**Full name of responsible person**

Dr. Mahmoud Djalali

**Position**

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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**