

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of the effects of omega-3 fatty acids supplementation on cigarette craving, urinary cotinine levels and oxidative stress index in heavy smokers

#### Protocol summary

##### Summary

**Objectives:** The aim of current study is to evaluate the effects of omega-3 fatty acids supplementation on nicotine dependence, cigarette craving, cigarette use per day, motivation to smoking cessation, urinary cotinine levels and oxidative stress index in cigarette smokers

**Design:** Randomized, double-blind, placebo-controlled, single-center. **Setting and conduct:** 54 subject heavy smokers in Urmia Emam Khomeini hospital will divide randomly into 2 groups, intervention group (receiving daily 5 gram Omega-3 supplements) and control group (daily 5 gram placebo miglyol) for 3 months. **Participants:** inclusion criteria are heavy smokers (a smoker who reports consuming 20 cigarettes or more per day); level of dependence above moderate (Fagerström test for nicotine dependence - FTND  $\geq 7$  points); depression below mild (Depression Anxiety Stress Scale 21 for depression - DASS 21  $< 9$  points); anxiety below moderate ( DASS 21  $< 9$  points); stress below moderate ( DASS 21  $< 18$  points); average motivation to quit smoking (Richmond test - RT  $> 5$  points); exclusion criteria including: psychiatric and neurodegenerative disorders; abusive use of alcohol or other substances. the urinary cotinine, total oxidant status(TOS), total antioxidant capacity (TAC) and oxidative stress index before and after 3 months intervention will compare between two groups. 24-hour dietary recalls will fill for participants.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092929508N5**

Registration date: **2016-12-28, 1395/10/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-28, 1395/10/08

##### Registrant information

###### Name

Rasoul Zarrin

###### Name of organization / entity

Urmia University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 3346 9935

###### Email address

rasoul.zarrin@uqconnect.edu.au

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Urmia University of Medical Sciences

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2017-01-20, 1395/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the effects of omega-3 fatty acids supplementation on cigarette craving, urinary cotinine levels and oxidative stress index in heavy smokers

##### Public title

Study of the effects of omega-3 fatty acids supplementation on cigarette craving, urinary cotinine levels and oxidative stress index in heavy smokers

#### **Purpose**

Other

#### **Inclusion/Exclusion criteria**

Inclusion criteria: heavy smokers (a smoker who reports consuming 20 cigarettes or more per day); level of dependence above moderate (Fagerström test for nicotine dependence - FTND  $\geq$  7 points); depression below mild (Depression Anxiety Stress Scale 21 for depression - DASS 21 < 9 points); anxiety below moderate ( DASS 21 < 9 points); stress below moderate ( DASS 21 <18 points); average motivation to quit smoking (Richmond test - RT > 5 points); Exclusion criteria: psychiatric and neurodegenerative disorders; abusive use of alcohol or other substances

#### **Age**

From **18 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **54**

#### **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 Urmia University of Medical Sciences

###### **Street address**

Urmia University of Medical Sciences, Resalat Ave, Jihad street, Urmia

###### **City**

Urmia

###### **Postal code**

57147

##### **Approval date**

2016-11-16, 1395/08/26

##### **Ethics committee reference number**

IR.umsu.vec.1395.305

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Heavy smoker

##### **ICD-10 code**

Z58.7

##### **ICD-10 code description**

Exposure to tobacco smoke

### **Primary outcomes**

#### **1**

##### **Description**

tobacco craving

##### **Timepoint**

before intervention, 3 months after intervention

##### **Method of measurement**

tobacco craving questionair- short form

#### **2**

##### **Description**

urinary cotinine

##### **Timepoint**

before intervention, 3 months after intervention

##### **Method of measurement**

nanogram/liter

#### **3**

##### **Description**

oxidative stress index

##### **Timepoint**

before intervention, 3 months after intervention

##### **Method of measurement**

micromol

#### **4**

##### **Description**

total oxidant status (TOS)

##### **Timepoint**

before intervention, 3 months after intervention

##### **Method of measurement**

$\mu\text{m}$

#### **5**

##### **Description**

total antioxidant capacity (TAC)

##### **Timepoint**

before intervention, 3 months after intervention

##### **Method of measurement**

$\mu\text{m}$

### **Secondary outcomes**

## 1

### Description

nicotine dependence

### Timepoint

before intervention, 3 months after intervention

### Method of measurement

fagerstrom test

## 2

### Description

cigarette use per day

### Timepoint

before intervention, 3 months after intervention

### Method of measurement

interview

## Intervention groups

### 1

#### Description

Intervention group: daily 5 gram Omega-3 supplements ,  
for 3 months

#### Category

Other

### 2

#### Description

control group: daily 5 gram placebo (miglyol), for 3  
months

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Khomeini Hospital

##### Full name of responsible person

Dr. Rasoul Zarrin

##### Street address

Emam KHomeini hospital, Ershad Street, Modarres  
Ave, Urmia, Iran

##### City

Urmia

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Urmia University of  
Medical Sciences

##### Full name of responsible person

Dr. Iraj Mohebbi

##### Street address

Urmia University of Medical Sciences, Jahad Street,  
Resalat Ave, Urmia

##### City

Urmia

##### 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, Urmia 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

Urmia University of Medical Sciences

#### Full name of responsible person

Dr. Rasoul Zarrin

#### Position

Assistant Professor of Nutrition

#### Other areas of specialty/work

#### Street address

Department of nutrition, Medicine Faculty, Nazlou  
Pardis , 11 km of Nazlou Road,Urmia,Iran

#### City

Urmia

#### Postal code

#### Phone

+98 44 3346 9935

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#### Email

rasoul.zarrin@uqconnect.edu.au;

wwzarrin@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

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Urmia University of Medical Sciences

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Dr. Rasoul Zarrin

#### Position

Assistant Professor of Nutrition

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Kiana Sadeghi Ardakani

**Position**

MSc student

**Other areas of specialty/work**

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## 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*