Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥ 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

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Rasoul Zarrin
Name of organization / entity
Urmia University of Medical Sciences
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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 ≥ 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, Jahad 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

µm

5

Description

total antioxidant capacity (TAC)

Timepoint

before intervention, 3 months after intervention

Method of measurement

µm

Secondary outcomes

1

Description
nicotine dependence
Timepoint
before intervention, 3 months after intervention
Method of measurement
fagesterstrom test

2

Description
sigarette 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
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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
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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