

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of taking Omega-3 pill on serum level of Interleukin-12 (IL-12) and C-Reactive Protein (CRP) in gas station employees in Isfahan

Protocol summary

Study aim

Evaluation and comparison of mean serum IL-12 and CRP levels in staff at the gas station before and after giving omega-3 pills in Isfahan

Design

In this study, 60 employees of the gas station in Isfahan who have been entered into the study are randomly selected from different gas stations in the city of Isfahan. Participants are randomly divided into two intervention and control groups, and a file is made for each case. Randomization method is random sampling method, clustering using random numbers table. This study is phase 3 clinical trial.

Settings and conduct

By random sampling, some gas stations are randomly selected from all parts of the city of Isfahan. The two groups in the study include gas station employees. In this study, the participant, researcher and evaluator of the outcome are kept blinded. The pills are in the same boxes, and the medication and placebo are coded so that the physician and the pharmacy and the patients do not know the codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Employees who work at the gas station for at least one year and are willing to participate in the study. Those who have not the systemic inflammatory diseases before they work in a gas station. Exclusion criteria: Employees who have changed their place of work or life less than one year of starting the study, at any time when one of the employees or members of the control group is not willing to participate in the research, If the subjects participating in the study suffer from another acute illness that increases the inflammatory factors of CRP and IL-12.

Intervention groups

Two groups are gas station staff. One of them receive omega-3 pills and another receive placebo.

Main outcome variables

Interleukin 12, C-reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171215037878N1**

Registration date: **2018-02-08, 1396/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

Registration date

2018-02-08, 1396/11/19

Registrant information

Name

Nafiseh Esmaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

n_esmaeil@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of taking Omega-3 pill on serum level of Interleukin-12 (IL-12) and C-Reactive Protein (CRP) in gas station employees in Isfahan

Public title

Omega-3 effect on gas station employees

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Employees who have worked at the gas station for at least one year. Satisfaction to participate in the study.

Exclusion criteria:

Having inflammatory systemic disease before working in a gas station

Age

No age limit

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Random random sampling method, clustering using random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participant, researcher and evaluator of the outcome are kept blinded. The pills are in the same boxes, and the medication and placebo are coded so that the physician and the pharmacy and the patients do not know the codes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-01-29, 1395/11/10

Ethics committee reference number

lr.mui.rec.1395.2.132

Health conditions studied**1****Description of health condition studied**

Systemic inflammatory diseases

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description****Timepoint****Method of measurement****2****Description**

Interleukin 12

Timepoint

At the beginning of the study, two months after taking omega-3 pills or placebo

Method of measurement

ELISA test

3**Description**

C-reactive protein

Timepoint

At the beginning of the study, two months after taking omega-3 pills or placebo

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Omega-3 pills, 3 times a day, for 2 months, orally

Category

Treatment - Drugs

2

Description

Control group: Placebo pills, 3 times a day, for 2 months, orally

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Different gas stations in Isfahan city

Full name of responsible person

Nafiseh Esmaeili

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Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Grant name

Grant code / Reference number

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

empty

Title of funding source

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Atar

Street address

Isfahan University of Medical Sciences, Hezarjerib

street, Isfahan, Iran

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nafiseh Esmaeili

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nafiseh Esmaeili

Position

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Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available