

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of conjugated linoleic acid and omega 3 fatty acids supplements on lipid profile, inflammatory factors and oxidative stress indices on patients with atherosclerosis

#### Protocol summary

##### Summary

This randomized clinical trial will be conducted to evaluate the effect of Conjugated linoleic acid and omega3 fatty acids supplements on atherosclerosis and its complications. Ninthly atoscholorotic patients with age>30 years, will be recruited from Emam Reza clinic in Shiraz, Iran. The patients will be randomly divided into 3 groups based on block randomization protocol: treatment group 1 will received3000 mg Conjugated linoleic acid as a 3 Soft gel capsules per day for eight weeks; treatment group 2 will take 1920 mg omega3 fatty acids as a 3 Soft gel capsules per day for eight weeks and control group will receive placebo a 3 Soft gel capsules per day for eight weeks. The patients will be followed for two months. At the beginning and 8 weeks after the start of the study, fasting blood samples will be taken. Lipid profile including cholesterol, triglycerides, LDL and HDL before and after the intervention will be compared in study groups

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103146067N1**

Registration date: **2011-05-04, 1390/02/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-05-04, 1390/02/14

##### Registrant information

###### Name

Dr. Mohammad Hasan Eftekhari Eftekhari

###### Name of organization / entity

School of health and nutrition, Shiraz University of Mediccal Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1725 1004

##### Email address

h\_eftekhari@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz university of medical sciences

##### Expected recruitment start date

2011-02-11, 1389/11/22

##### Expected recruitment end date

2011-03-01, 1389/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of conjugated linoleic acid and omega 3 fatty acids supplements on lipid profile, inflammatory factors and oxidative stress indices on patients with atherosclerosis

##### Public title

The effect of conjugated linoleic acid and omega 3 fatty acids on patients with atherosclerosis.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with Atherosclerosis with Age more than30 years old, 24.5>Body Mass Index>18.5, use of stable dosage medication for hyperlipidemia in

study period, patients with history of stable angina, heart attack and bypass surgery. Exclusion criteria: Having Acute heart failure , Arrhythmia, Acute complications of atherosclerosis, using any supplement such as vitamin C, E, Omega3 during and six months before the study, pregnancy , UVB exposure with therapeutic goals and diabetes mellitus

#### Age

From **30 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences

##### City

Shiraz

##### Postal code

#### Approval date

2011-02-10, 1389/11/21

#### Ethics committee reference number

89-5407

## Health conditions studied

### 1

#### Description of health condition studied

Heart disease

#### ICD-10 code

I25.1

#### ICD-10 code description

بیماری قلبی آترواسکلروتیک

## Primary outcomes

### 1

#### Description

Lipid profile

#### Timepoint

Before and after intervention

#### Method of measurement

Auto Analyzor

## Secondary outcomes

### 1

#### Description

GSH-X(Glutathione peroxidase)

#### Timepoint

Before and after intervention

#### Method of measurement

ELIZA

### 2

#### Description

MDA (Malondialdehyde)

#### Timepoint

Before and after intervention

#### Method of measurement

Spectrophotometry

### 3

#### Description

hs-CRP(high sensitive c-reactive protein)

#### Timepoint

Before and after intervention

#### Method of measurement

ELIZA

### 4

#### Description

Interleukin 6

#### Timepoint

Before and after intervention

#### Method of measurement

RIA kit

## Intervention groups

### 1

#### Description

Conjugated linoleic acid intake,3000 mg per day, for 2months , 3 capsule per day, each capsule contain 1000mg cnjugated linoleic acid

#### Category

Treatment - Drugs

## 2

### Description

Omega 3 fatty acids intake,1920mg per day for 2 months , 3 capsule per day, each capsule contain 640 mg,omega3 fatty acids

### Category

Treatment - Drugs

## 3

### Description

Placebo intake for 2 months , 3 capsule per day

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza clinic

##### Full name of responsible person

##### Street address

##### City

shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz university of medical sciences

##### Full name of responsible person

Dr. Mohammad Hossein Dabaghmanesh

##### Street address

Shiraz university of medical sciences

##### City

shiraz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shiraz 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

School of health and nutrition, Shiraz University of Mediccal Sciences

#### Full name of responsible person

fereshte aliasghari

#### Position

MSc. student of nutrition

#### Other areas of specialty/work

#### Street address

Department of nutrition, School of health and nutrition, Shiraz University of Mediccal Sciences

#### City

shiraz

#### Postal code

7153675541

#### Phone

+98 71 1725 1001

#### Fax

+98 71 1726 0225

#### Email

f.aliasghary@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of health and nutrition, Shiraz University of Mediccal Sciences

#### Full name of responsible person

Dr. Mohammad Hassan Eftekhari

#### Position

PHD of nutrition,associate professor of nutrition department

#### Other areas of specialty/work

#### Street address

Department of nutrition, School of health and nutrition, Shiraz University of Mediccal Sciences

#### City

Shiraz

#### Postal code

7153675541

#### Phone

+98 71 1725 1001

#### Fax

+98 71 1726 0225

#### Email

eftekhari@sums.ac.ir; h\_efftekhari@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Shiraz Universoty of Medical Sciences

#### Full name of responsible person

fereshte aliasghari

#### Position

MSc student

**Other areas of specialty/work**

**Street address**

Shiraz, Shiraz University of Medical Sciences, School  
of health and nutrition

**City**

Shiraz

**Postal code**

**Phone**

**Fax**

**Email**

f.aliasghary@yahoo.com

**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*