

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparing the effects of consumption of Canola oil and Sunflower oil on serum markers of bone metabolism and inflammation in patients with osteoporosis

#### Protocol summary

##### Summary

The aim of this study is comparing the effects of consumption of Canola oil and Sunflower oil on serum markers of bone metabolism and inflammation in patients with osteoporosis. To do this, 40 osteoporotic patients will be selected. Patients will be assigned randomly to one of the two intervention groups. 1. Canola oil Plain 2. Sunflower oil. Each patient will consume 20 percent of diets oil from this oils every day for 3 months. At the first and last visits, dietary and laboratory assessments will be performed for all patients. Primary outcomes are improvement in, serum markers of bone metabolism and inflammation and secondary outcome is prevention of osteoporosis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012084010N5**

Registration date: **2011-04-14, 1390/01/25**

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

Last update:

Update count: **0**

##### Registration date

2011-04-14, 1390/01/25

##### Registrant information

###### Name

Azita Hekmatdoost

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
National Institute of Nutrition Research

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2293 0824

###### Email address

hekmat@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

National Nutrition and Food Technology Research  
Institute, Shahid Beheshti University of Medical Sciences  
& Health Services

##### Expected recruitment start date

2010-08-23, 1389/06/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effects of consumption of Canola oil and Sunflower oil on serum markers of bone metabolism and inflammation in patients with osteoporosis

##### Public title

Canola oil and osteoporosis

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: to be keen to corporation, Age $\geq$ 50 years, osteoporosis based on dansitometry, BMI= $<$ 30, not consumption of canola oil within the last two months. Exclusion criteria: any other concomitant disease such as diabetes, renal, inflammatory, heart, hepatic, allergy, parathyroid, and malignancies, fracture, receiving any anti-inflammatory and chemotherapy drugs.

##### Age

From **50 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

National Nutrition and Food Technology Research  
Institute, Shahid Beheshti University of Medical Sci

**Street address**

West Arghavan St., Farahzadi Blvd., Shahrak Qods

**City**

Tehran

**Postal code**

1981619573

**Approval date**

2011-03-05, 1389/12/14

**Ethics committee reference number**

39

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

Osteoporosis

**ICD-10 code**

M81

**ICD-10 code description**

Osteoporosis without pathological fracture

**Primary outcomes****1****Description**

Improvement of w-3 fatty acid status of diet

**Timepoint**

Baseline and 3 month after intervention

**Method of measurement**

Dietary assessments

**Secondary outcomes****1****Description**

Improvement of inflammation markers

**Timepoint**

Baseline and 3 month after intervention

**Method of measurement**

Serum IL-1,IL-4, IL-6 and TNF- $\alpha$  concentrations

**2****Description**

Improvement of bone metabolism markers

**Timepoint**

Baseline and 3 month after intervention

**Method of measurement**

Serum osteocalcin, bone alkaline phosphatase, telopeptide  
collagen1

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

Control group: Sunflower oil (20 percent of diets oil)

**Category**

Other

**2****Description**

Interventional group: Canola oil (20 percent of diets oil)

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

National nutrition and food technology research  
institute

**Full name of responsible person**

Dr. Rahebe Shakerhosseini

**Street address**

West Arghavan St., Farahzadi Blvd., Shahrak Qods

**City**

Tehran

**Sponsors / Funding sources**

# 1

## Sponsor

### Name of organization / entity

National Nutrition and Food Technology Research  
Institute, Shahid Beheshti University of Medical Sci

### Full name of responsible person

Dr. Mohammad Hossein Azizi

### Street address

West Arghavan St., farahzadi Blvd., Shahrak Qods

### City

Tehran

## Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

National Nutrition and Food Technology Research  
Institute, Shahid Beheshti University of Medical Sci

### 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

National Nutrition and Food Technology Research  
Institute, Shahid Beheshti University of Medical Sci

#### Full name of responsible person

Mahboube Azemati

#### Position

PhD student in Nutrition

#### Other areas of specialty/work

#### Street address

West Arghavan St., Farahzadi Blvd., Shahrak Qods

#### City

Tehran

#### Postal code

#### Phone

+98 912 370 5131

#### Fax

#### Email

drazemati@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

National Nutrition and Food Technology Research  
Institute, Shahid Beheshti University of Medical Sci

#### Full name of responsible person

Dr. Rahebe Shakerhosseini

#### Position

PhD in nutrition

#### Other areas of specialty/work

#### Street address

West Arghavan St., Farahzadi Blvd., Shahrak Qods

#### City

Tehran

#### Postal code

#### Phone

+98 21 2237 6471

#### Fax

#### Email

rshakerhosseini@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

## 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*