

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

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Iran (Islamic Republic of)

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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- α 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

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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

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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

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

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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