

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of whole wheat and white bread on Serum Lipid profile, Malondialdehyde, and C reactive protein in over weight and obese patients with coronary stent

Protocol summary

Summary

We aim to examine the effect of whole wheat VS. white bread on serum lipid profiles, Malondialdehyde; and C reactive protein in overweight and obese patients with Coronary stent. Eighty men and women who had stent and BMI ≥ 25 by using block randomization were be divided into two groups. Intervention group consumed 150 g of whole-wheat bread daily accompanied with a low-calorie diet and the Control group consumed 150 g of white-wheat bread as well as a low-calorie diet. The intervention was continued for 3 months. All groups were advised not to change their physical activity during the study. Primary outcome (BMI, lipid profile, MDA, hs_CRP, blood pressure, waist and hip circumference) were evaluated at baseline and end of the study. Data will be analysis with SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021021039N1**

Registration date: **2015-08-16, 1394/05/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-16, 1394/05/25

Registrant information

Name

Razieh Khorramnazari

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

khoramnazari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2015-02-10, 1393/11/21

Expected recruitment end date

2015-07-12, 1394/04/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of whole wheat and white bread on Serum Lipid profile, Malondialdehyde, and C reactive protein in over weight and obese patients with coronary stent

Public title

Effect of Whole bread on patients with Coronary diseases

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate, having stent for Atherosclerosis, Body Mass Index ≥ 25 , whole grain product consumption ≤ 3 servings/d, not having any kidney, liver or thyroid diseases, nonsmoker, pregnant or lactating. Exclusion criteria: poor participation, lack of adherence to the study protocol

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

7th floor, Shiraz University main Office, Zand St.

City

Shiraz

Postal code**Approval date**

2015-02-03, 1393/11/14

Ethics committee reference number

CT- 9372-7342

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

Patients with Coronary stent

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

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

Lipid profile

Timepoint

At the beginning and end of the intervention

Method of measurement

By use of bt1500 set and Pars test kit

2**Description**

hs_CRP

Timepoint

At the beginning and end of the intervention

Method of measurement

ELISA

3**Description**

MDA

Timepoint

At the beginning and end of the intervention

Method of measurement

Spectroscopy and photometric method

4**Description**

Blood Pressure

Timepoint

At the beginning and end of the intervention

Method of measurement

mmHg-piezometer

5**Description**

Body Mass Index

Timepoint

At the beginning and end of the intervention

Method of measurement

BMI will be calculated as weight (kg)/ height (m)²

6**Description**

Waist circumference

Timepoint

At the beginning and end of the intervention

Method of measurement

Tape measure

7**Description**

Hip circumference

Timepoint

At the beginning and end of the intervention

Method of measurement

Tape measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group consumed 150 g of whole-wheat bread daily as well as a low-calorie diet. Patients consumed 90 g of whole wheat bread for breakfast and 60 g at dinner. The intervention continued for 3 months. Bread was given to the participants weekly. The breads is produced by Hadith Factory in Shiraz. (Health produce ministry.: 36/12435, Lic No.: 817072, Health benefit ministry No.: 9137)

Category

Prevention

2

Description

Control group consumed 150 g of white_wheat_bread daily as well as a low-calorie diet. Patients consumed 90 g of the bread at breakfast and 60 g for dinner. The intervention continued for 3 months.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Clinic

Full name of responsible person

Razieh Khorramnazari

Street address

Namazi Square, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor off Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyyed Basir Hashemi

Street address

7th floor, Shiraz University main Office, Zand St.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor off Research, 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 Nutrition and Food Science

Full name of responsible person

Razieh Khorramnazari

Position

MS Candidate of Nutrition

Other areas of specialty/work

Street address

School of Nutrition and Food Science. Across from Bargh Stadium, Razi Blvd.

City

Shiraz

Postal code

Phone

0098 71_372_51001

Fax

Email

khoramnazari@sums.ac.ir rkhoramnazari@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nutrition and Food Science

Full name of responsible person

Razieh Khorramnazari

Position

MS Candidate in Nutrition

Other areas of specialty/work

Street address

School of Nutrition and Food Science. Across from Bargh Stadium, Razi Blvd.

City

Shiraz

Postal code

Phone

0098 71_372_51001

Fax

Email

khoramnazari@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nutrition and Food Science

Full name of responsible person

Razieh Khorramnazari

Position

MS Candidate of Nutrition

Other areas of specialty/work**Street address**

School of Nutrition and Food Science. Across from
Bargh Stadium, Razi Blvd.

City

Shiraz

Postal code**Phone**

0098 71_372_51001

Fax**Email**

khoramnazari@sums.ac.ir

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