

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The Effect of crude pistachio consumption on lipid parameters, glucose blood level, inflammatory and Oxidative Stress factors in with type 2 diabetes.

#### Protocol summary

##### Summary

This study will investigate the effect of crude pistachio consumption on fat and blood sugar levels, inflammatory and oxidative stress factors in patients with type 2 diabetes. Exclusion criteria include patients with kidney, liver and respiratory disorders, history of allergy to pistachio, smoking and alcohol consumption, female patients undergoing hormone therapy, patients under treatment with insulin, becoming exposed to severe stress, depression and recreational drug use, disorder of kidney stones. Inclusion criteria include awareness of time and place and the ability to speak and understand Persian. In this randomised clinical trial, from type of double-blind and crossover will participate 48 patients with diabetes (one among with sex segregation) in the experimental (24 patients) and controls (n = 24) groups. This study will be performed in two phases and any phase will extend 8 weeks. After the first phase, the intervention will be discontinued for two weeks and groups will change. At the beginning and end of each two phases will be completed questionnaire reminiscent diet for 24 hours, for a holiday and a normal day, and the blood pressure, height and body weight and blood sugar, fasting insulin levels, cholesterol, LDL, HDL and triglycerides, total antioxidant and CRP was measured for both groups. From patients in both groups will be asked to not change the usual diet, physical activity and lifestyle habits during the study. From experimental group patients will be asked in their daily snack are used from 50 grams of raw pistachio without the skin for 8 weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111155543N3**

Registration date: **2012-02-18, 1390/11/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-02-18, 1390/11/29

##### Registrant information

###### Name

Saeide Heidari

###### Name of organization / entity

School nursing and midwifery, Qom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 1292 4521

###### Email address

sheidari@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qom University of Medical Sciences

##### Expected recruitment start date

2012-02-20, 1390/12/01

##### Expected recruitment end date

2012-10-22, 1391/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of crude pistachio consumption on lipid

parameters, glucose blood level, inflammatory and Oxidative Stress factors in with type 2 diabetes.

## Public title

The effect of pistachio consumption on laboratory parameters in patients with type 2 diabetes

## Purpose

Prevention

## Inclusion/Exclusion criteria

Exclusion criteria: patients with kidney, liver and respiratory therapy, history of allergy to pistachio, smoking and alcohol consumption, female patients undergoing hormone therapy, patients treated with insulin, becoming exposed to severe stress (infections, diabetic foot surgery, severe emotional stress), depression and recreational drug use, risk of kidney stones inclusion criteria: diabetes, according to physician, willingness to participate in the study, awareness to time and place, not being addiction to Narcotics and recreational drugs, the ability to speak and understand Persian.

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Qom University of Medical Sciences

##### Street address

Qom University of Medical Sciences, Lavasani St.,  
Qom

##### City

Qom

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

## Ethics committee reference number

18958/34/پ

## Health conditions studied

### 1

#### Description of health condition studied

diabetes

#### ICD-10 code

E10-E14

#### ICD-10 code description

Diabetes mellitus

## Primary outcomes

### 1

#### Description

Fasting Blood Sugar

#### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

#### Method of measurement

blood test (Mg per deciliter)

### 2

#### Description

triglyceride

#### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

#### Method of measurement

blood test (Mg per deciliter)

### 3

#### Description

Low-density lipoprotein (LDL)

#### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

#### Method of measurement

blood test (Mg per deciliter)

### 4

#### Description

High-density lipoprotein (HDL)

#### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

#### Method of measurement

blood test (Mg per deciliter)

## 5

### Description

TOTAL cholesterol

### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

### Method of measurement

blood test (Mg per deciliter)

## 6

### Description

total antioxidant

### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

### Method of measurement

blood test (pg/ml)

## 7

### Description

C-reactive protein (CRP)

### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

### Method of measurement

blood test (Mg per deciliter)

## Secondary outcomes

### 1

#### Description

Blood Pressure

#### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

#### Method of measurement

Using a barometer (mmHg)

### 2

#### Description

body mass index (BMI)

#### Timepoint

Before the intervention, 8 weeks after the intervention, two weeks after the intervention, 10 weeks after intervention

#### Method of measurement

Weight in kilograms divided by height in meters squared

### 3

#### Description

fasting blood insulin level

#### Timepoint

Before the intervention, 8 weeks after the intervention,

two weeks after the intervention, 10 weeks after intervention

#### Method of measurement

pg/ml

## Intervention groups

### 1

#### Description

From experimental group patients will be asked to not change the usual diet, physical activity and lifestyle habits during the study and in their daily snack (morning and Evening) ) are used from 50 grams of raw pistachio without the skin for 8 weeks.

#### Category

Lifestyle

### 2

#### Description

From experimental group patients will be asked to not change the usual diet, physical activity and lifestyle habits during the study.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti hospital

##### Full name of responsible person

Saeide Heidari

##### Street address

Nursing Department, School Nursing and Midwifery, Lavasani St., Qom

##### City

Qom

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qom University of Medical Sciences

##### Full name of responsible person

Dr Ali-Reza Koohpayee

##### Street address

Qom University of Medical Sciences, Lavasani St., Qom

##### City

Qom

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Qom 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**

Qom University of Medical Sciences

**Full name of responsible person**

Saeide Heidari

**Position**

Master of Nursing / faculty

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

School Nursing and Midwifery, Lavasani St., Qom

**City**

Qom

**Postal code****Phone**

+98 25 1770 4233

**Fax****Email**

heidari\_saeide@yahoo.com- sheidari@muq.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qom university of medical science

**Full name of responsible person**

Saeide Heidari

**Position**

Master of Nursing / faculty

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

School Nursing and Midwifery, Lavasani St., Qom

**City**

Qom

**Postal code****Phone**

+98 25 1770 4233

**Fax****Email**

heidari\_saeide@yahoo.com sheidari@muq.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Qom University of Medical Sciences

**Full name of responsible person**

Saeide Heidari

**Position**

Master of Nursing/ faculty

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

School Nursing and Midwifery, Lavasani St., Qom

**City**

Qom

**Postal code****Phone**

+98 25 1770 4233

**Fax****Email**

heidari\_saeide@yahoo.com sheidari@muq.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*