Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 investigated 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 participated 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 phase and any phase 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 phase 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)

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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
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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
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
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Saeide Heidari
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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