Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Investigate the effects of Pomegranate Extract Supplementation on Inflammation in Overweight and Obese Individuals

Protocol summary

Summary

The aim of the present study was to determine the effects of thirty days of pomegranate extract oral supplementation on plasma inflammatory and oxidative stress bio-markers of the overweight and obese individuals. In this randomized, double-blind, placebo-controlled study forty-eight healthy obese and overweight participants who went to the Shariati hospital for a regular check up and did not have any diseases and also did not use any pharmaceutical drugs as well as dietary supplements within the 3 months prior to the study; were randomly assigned to receive either 1000 mg of pomegranate extract (PE), or a placebo (PL), daily for 30 days. At baseline, and after 30 days of treatment 10 ml blood was collected after a 12hr fasting state. In this study, plasma concentrations of MDA, IL-6, hs-CRP were assessed, as were the levels of serum lipids, glucose and insulin. The study was blind for both the participants and the researchers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062722934N1**
Registration date: **2015-07-24, 1394/05/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name

Banafshe Hosseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5805

Email address

b-hosseini@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effects of Pomegranate Extract Supplementation on Inflammation in Overweight and Obese Individuals

Public title

Investigate the effects of Pomegranate Extract Supplementation on Inflammation in Overweight and Obese Individuals

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Willingness to participation; Between the age 30-60 years old and Having a BMI within the range 25-40 kgm2; does not have a history of use of any dietary supplements within 3 months prior to the study; does not smoking or alcohol consumption; does not take any cholesterol; triglyceride as well as blood lowering medicine; does not suffer from any acute condition which

needs treatment; does not suffer from metabolic stress, infection or inflammation; does not suffer from abnormal liver or kidney function; without any history of heart disease; does not take estrogen and progesterone; does not suffer from poly cyctic ovarian syndrome; not be pregnant or does not lactating. Exclusion criteria:; meet any aforementioned condition which can exclude the participants from the study ; present any changes in the diet or physical activity.

Age
From **30 years** old to **60 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
Used

Assignment
Parallel

Other design features
A stratified randomized permuted block (with block size randomly varied between 2 or 4) was generated by a biostatistician.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Enqelab Street

City
Tehran

Postal code

Approval date
2015-02-01, 1393/11/12

Ethics committee reference number
93-04-161-27760

Health conditions studied

1

Description of health condition studied
Overweight and obesity

ICD-10 code
E66.9

ICD-10 code description
Simple obesity NOS

Primary outcomes

1

Description
IL-6

Timepoint
30 days

Method of measurement
IL-6 was measured by ELISA kits (BioCore, Germany)

2

Description
MDA

Timepoint
30 days

Method of measurement
IL-6 was measured by ELISA kits (BioCore, Germany)

Secondary outcomes

1

Description
hs-CRP

Timepoint
30 days

Method of measurement
ELISA method using using commercial ELISA kit (Biochem, Ontario, Canada)

2

Description
Glucose

Timepoint
30 days

Method of measurement
determined through an enzymatic calorimetric method using glucose oxidase by commercial kits (Pars azmoon, Tehran, Iran)

3

Description
Cholestrol

Timepoint
30 days

Method of measurement
determined through an enzymatic calorimetric method using glucose oxidase by commercial kits (Pars azmoon, Tehran, Iran)

4

Description
HDL-C
Timepoint
30 days
Method of measurement
determined through an enzymatic calorimetric method using glucose oxidase by commercial kits (Pars azmoon, Tehran, Iran)

5

Description
LDL-C
Timepoint
30 days
Method of measurement
determined through an enzymatic calorimetric method using glucose oxidase by commercial kits (Pars azmoon, Tehran, Iran)

6

Description
Insulin
Timepoint
30 days
Method of measurement
determined through an enzymatic calorimetric method using glucose oxidase by commercial kits (Pars azmoon, Tehran, Iran)

Intervention groups

1

Description
Intervention group: In the intervention group 1000 mg pomegranate extract through two capsules one of each had 500 mg was consumed daily for 30 days.
Category
Other

2

Description
Control group: In the control group, 1000 mg identical placebo made by pure crystalline was consumed daily through two capsules one of each had 500 mg placebo for 30 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ahmad Saedi
Street address
North Karegar Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Masoud Yunesian
Street address
Enqelab Street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ahmad Saedi
Position
Associate professor
Other areas of specialty/work
Street address
Enqelab Street
City
Tehran
Postal code
Phone
+98 21 8895 5805
Fax
Email
a_saedi@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ahmad Saedi
Position
Associate Professor
Other areas of specialty/work
Street address
Enqelab Sreet
City
Tehran
Postal code
Phone
+98 21 8895 5805
Fax
Email
a_saedi@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ahmad Saedi
Position
Associate Professor
Other areas of specialty/work
Street address
Enqelab Street
City
Tehran
Postal code
Phone
+98 21 8895 5805
Fax
Email
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