

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effects of pomegranate seed (PSO) with resistance exercise on insulin resistance and cardiovascular risk factors in non-athletic men

#### Protocol summary

##### Summary

Some cell culture and animal studies have reported that pomegranate seed (PSO) have several health related benefits, but there is not enough information on the impact combined with exercise. Therefore, in this study was considered the effect of supplementation with pomegranate seed oil with resistance exercise on insulin resistance and lipid profile in non-athletes men. In a semi-experimental study with a double-blind randomized 14 non-athletes male were divided into two groups: exercise+supplementation (n = 7) and training+placebo (n = 7). Both groups performed resistance training program for 4 weeks (3 sessions per week). The experimental group consumed 2 capsules of 400 mg of pomegranate seed oil and the control group received 2 placebo. Glucose, fasting insulin, total cholesterol, triglycerides, LDL-C, HDL-C, were measured at the beginning and end of the study. Insulin resistance was estimated by the homeostasis Formula (HOMA-IR).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092730023N1**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-02-10, 1395/11/22

##### Registrant information

###### Name

Khalilullah Moonikh

###### Name of organization / entity

Rajai Teacher Training University

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Researchers

##### Expected recruitment start date

2016-12-10, 1395/09/20

##### Expected recruitment end date

2016-12-20, 1395/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of pomegranate seed (PSO) with resistance exercise on insulin resistance and cardiovascular risk factors in non-athletic men

##### Public title

The effects of pomegranate seed (PSO) with resistance exercise on insulin resistance and cardiovascular risk factors in non-athletic men

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: Healthy young men with no previous record of any specific drug use; without experience of regular physical activity in two year before beginning of the study. Exclusion Criteria: Unhealthy; Doing regular exercise during the last two years.

##### Age

From **21 years** old to **23 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **14**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Sport Sciences Research Institute of IRAN

**Street address**

NO 3, 5th alley, Miremad Ave, Tehran

**City**

Tehran

**Postal code****Approval date**

2015-11-04, 1394/08/13

**Ethics committee reference number**

IR.SSRI.IREC.1395.20

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

Obesity

**ICD-10 code**

E66

**ICD-10 code description**

Obesity

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

Fasting insulin

**Timepoint**

Before and after 4 weeks

**Method of measurement**

Elisa

**Secondary outcomes****1****Description**

Lipid profiles (total cholesterol, triglycerides, and low high-density cholesterol)

**Timepoint**

Before and after 4 weeks

**Method of measurement**

Enzymatic

**2****Description**

Insulin resistance index

**Timepoint**

Before and after 4 weeks

**Method of measurement**

Elisa

**Intervention groups****1****Description**

400 mg doses of 2 capsules of pomegranate seed oil + RT

**Category**

Treatment - Drugs

**2****Description**

2 + placebo control group resistance training

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rajai Teacher Training University

**Full name of responsible person**

Fereshte Shahidy

**Street address**

Rajai Teacher Training University, Lavizan, Tehran

**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rajai Teacher Training University

**Full name of responsible person**

Khalil ollah Moonikh

**Street address**Rajai Teacher Training University, St.Shabanlo,  
Lavizan, Tehran**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Rajai Teacher Training University

**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**

Rajai Teacher Training University

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PhD student of exercise physiology

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**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*