

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effects of Pine Bark Extract supplementation and Weight Loss Diet On Resting Energy Expenditure, Body Composition and Metabolic Syndrome criteria in Obese Women

Protocol summary

Summary

The aim of this study is the examination of pine bark extract supplementation and weight loss diet on resting energy expenditure, body composition and metabolic syndrome criteria in obese women. Inclusion criteria are being female, age of 18-45 and body mass index of 30-35. Exclusion criteria are included of failure to follow the weight loss diet, unwillingness to cooperate, presence of any clinical disorders and pregnancy. Fifty obese healthy women will enroll in this randomized clinical trial study who randomly allocate in 2 groups. Both of groups receive weight loss diet in addition to 150 mg pine bark extract in intervention group and placebo in control group (starch powder) over a 2 month period. The body composition (Bioelectrical Impedance Analysis method), Resting Energy Expenditure (indirect calorimetric method) and metabolic syndrome criteria (Triglyceride, Weight circumstance, Cholesterol, Blood pressure, Blood sugar) will measure at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062628637N1**

Registration date: **2016-07-07, 1395/04/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-07, 1395/04/17

Registrant information

Name

Mohsen Sedighiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

m-sedighiyan@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

- Tehran University Medical of Sciences - Endocrinology and Metabolism Research Institute

Expected recruitment start date

2016-06-20, 1395/03/31

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Pine Bark Extract supplementation and Weight Loss Diet On Resting Energy Expenditure, Body Composition and Metabolic Syndrome criteria in Obese Women

Public title

The effects of pine bark extract and weight loss diet on obesity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: body mass index (BMI) > 30 and <35 kg/m²; age of 18-45; being female Exclusion criteria: Report any side effects; Unwillingness to cooperate; Use

of less than 90 percent of supplements during the study intervention; Failure to follow the regime; Pregnancy, lactation or menopause; Use of any medication; Presence of any clinical disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Endocrinology and Metabolism Research Institute

Street address

Floor 5, Shariati Hospital, Kargar Shomali Street

City

Tehran

Postal code

Approval date

2015-11-09, 1394/08/18

Ethics committee reference number

IR.TUMS.EMRI.REC.1394.007

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Waist circumference

Timepoint

at the beginning and end of study

Method of measurement

meter (cm)

2

Description

Systolic Blood Pressure

Timepoint

at the beginning and end of study

Method of measurement

Barometer (mmhg)

3

Description

Diastolic Blood Pressure

Timepoint

at the beginning and end of study

Method of measurement

Barometer (mmhg)

4

Description

serum HDL-c

Timepoint

at the beginning and end of study

Method of measurement

enzymic (mg/dl)

5

Description

serum triglyceride (TG)

Timepoint

at the beginning and end of study

Method of measurement

enzymic (mg/dl)

6

Description

Fasting Blood Sugar (FBS)

Timepoint

at the beginning and end of study

Method of measurement

enzymic (mg/dl)

7

Description

Resting Energy Expenditure

Timepoint

at the beginning and end of study

Method of measurement

indirect calorimetric

8

Description

fat mass

Timepoint

at the beginning and end of study

Method of measurement

Bioelectrical Impedance Analysis (BIA)

9

Description

fat free mass

Timepoint

at the beginning and end of study

Method of measurement

Bioelectrical Impedance Analysis (BIA)

10

Description

total body water

Timepoint

at the beginning and end of study

Method of measurement

Bioelectrical Impedance Analysis (BIA)

Secondary outcomes

1

Description

weight

Timepoint

at the beginning and at the end of study

Method of measurement

seca scale

2

Description

Hip circumference

Timepoint

at the beginning and at the end of study

Method of measurement

meter (cm)

3

Description

Waist to Hip ratio (WHR)

Timepoint

at the beginning and at the end of study

Method of measurement

Calculation

4

Description

Body Mass Index (BMI)

Timepoint

at the beginning and at the end of study

Method of measurement

Calculation

Intervention groups

1

Description

The intervention group receive one capsule with 150 mg pine bark extract, daily, for 2 month + weight loss diet

Category

Treatment - Drugs

2

Description

The control group receive one capsule contain of starch powder, daily, for 2 month + weight loss diet

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Research Institute in Shariati hospital

Full name of responsible person

Ms. Ehsaneh Taheri

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology and Metabolism Research Institute

Full name of responsible person

Dr. Hossein Adibi

Street address

floor 5, Shariati hospital, Kargar Shomali street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology and Metabolism Research Institute

Proportion provided by this source

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***2****Sponsor****Name of organization / entity**

School of Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Full name of responsible person

Ms. Fatemeh Javadi

Street address

44 Hojat Dost St, Naderi St, Enghelab Ave

City

Tehran

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

Yes

Title of funding source

School of Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Proportion provided by this source**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 Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Full name of responsible person

Mr. Mohsen Sedighian

Position

Msater of Sciences of Nutrition Sciences and dietetics

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

44 Hojat Dost St, Naderi St, Keshavarz Boulevard

City

Tehran

Postal code**Phone**

+98 21 8895 5975

Fax**Email**

m.sedighian86@gmail.com-
sedighian@razi.tums.ac.ir

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

School of Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Full name of responsible person

Dr.Saeed Hosseini

Position

MD/ Ph.D

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

44 Hojat Dost St, Naderi St, Keshavarz Boulevard

City

Tehran

Postal code**Phone**

+98 21 8895 5975

Fax**Email**

saeedhmdphd@hotmail.com

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

School of Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Full name of responsible person

Mr. Mohsen Sedighian

Position

Msc in Nutrition Sciences and Dietetics

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

44 Hojat Dost St, Naderi St, Keshavarz Boulevard

City

Tehran

Postal code**Phone**

+98 21 8895 5742

Fax**Email**

m.sedighian86@gmail.com

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*