

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Bunium pericum capsule (a Persian medicine product) on anthropometric indices and biochemical factors in overweight and obese women.

Protocol summary

Study aim

Evaluating the effects of Bunium pericum capsule on anthropometric and biochemical indices in overweight and obese women

Design

three-blind randomized controlled clinical trial. randomization with the R4.0.2 software. sample size=64 (32 patients in each group).

Settings and conduct

The location of the project will be Ahmadi Health Center affiliated with the Faculty of Persian Medicine of Tehran University of Medical Sciences. Capsules containing the drug and placebo will be exactly the same in shape, color and size and will be stored in dark bottles. The bottles will be named A and B, and researchers, volunteers, outcome assessors, and statistical data analysts will not know which group of drugs and which placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women Age 20-40 Women older than 40 will be included if they have a normal mammogram. BMI 25 -34.9 kg / m² Non-inclusion criteria: Pregnancy, lactation Menopause Hypermenorrhea Regular use of teas or other herbal medicines Smoking, alcohol consumption History of any types of malignancies Asthma Allergies Hormonal disorders The chronic liver, heart, kidney, thyroid diseases, diabetes mellitus, hypertension, infectious diseases Family history of Breast or endometrial cancer in first-degree relatives Regular use of acetaminophen (paracetamol) or anticoagulants or antiplatelet drugs such as aspirin, warfarin, heparin Use of weight-loss diets or weight loss drugs during the last 6 months

Intervention groups

Each volunteer will take 2000 mg daily (one capsule 30 minutes before breakfast, two capsules 30 minutes before lunch and, one capsule 30 minutes before dinner)

drug or placebo for 8 weeks. All participants in both groups will receive a diet designed by a nutritionist.

Main outcome variables

Weight, BMI, Waist size, Hip size, Waist to hip ratio Food intake Fasting Blood Sugar, Blood lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210510051241N1**

Registration date: **2021-05-25, 1400/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-25, 1400/03/04**

Update count: **0**

Registration date

2021-05-25, 1400/03/04

Registrant information

Name

Zahra Aghabeigloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7725 6499

Email address

aghabeigloo@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Bunium pericum capsule (a Persian medicine product) on anthropometric indices and biochemical factors in overweight and obese women.

Public title

The effects of Bunium pericum capsule on obesity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Female only Age 20 to 40 years Women over the age of 40 will be included in the study if they have a normal mammogram. BMI between 25 and 34.9 kg / m²

Exclusion criteria:

Pregnancy and lactation Menopause Hypermenorrhea, Menorrhagia Regular use of teas or other herbal medicines Smoking or alcohol consumption History of any types of malignancies Asthma History of any allergies History of any hormonal disorders History of chronic liver, heart, kidney, thyroid diseases, diabetes mellitus, hypertension, infectious diseases Family history of Breast or endometrial cancer in first-degree relatives Regular use of acetaminophen (paracetamol) or anticoagulants or antiplatelet drugs such as aspirin, warfarin, heparin and ... Use of weight loss diets or weight loss drugs during the last 6 months

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

R4.0.2 software A randomized list was needed to randomly assign individuals. We used R software to prepare this list, which included 0 and 1. In this software, random samples were generated from a binomial distribution with $P = 0.5$ equal to the total number of samples (64 people). $((64,0.5) A = \text{rbinom})$ A vector of these numbers consists of 64 randomly arranged numbers 0 and 1 for random actions of the drug or placebo group. The probability $P = 0.5$ leads to an equal chance of each person being in one of these groups. At

the end, the numbers 1 and 0 are counted to match 32 people in each group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as triple blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

School of Medicine- Tehran University of Medical Sciences (Biomedical Research Ethics Committee)

Street address

1th Floor, Medicine School, Poursina St, Qods St, Enghelab St.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.145

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

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

2**Description of health condition studied**

Overweight

ICD-10 code

5B80.0Z

ICD-10 code description

Overweight or localised adiposity

Primary outcomes

1

Description

Weight

Timepoint

At the beginning of the study (before the intervention), 4 weeks and 8 weeks after the intervention

Method of measurement

Digital scales

2

Description

Waist circumference size

Timepoint

At the beginning of the study (before the intervention), 4 weeks and 8 weeks after the intervention

Method of measurement

Tape measure

3

Description

Hip circumference size

Timepoint

At the beginning of the study (before the intervention), 4 weeks and 8 weeks after the intervention

Method of measurement

Tape measure

4

Description

Body Mass Index (BMI)

Timepoint

At the beginning of the study (before the intervention), 4 weeks and 8 weeks after the intervention

Method of measurement

Ratio of weight to height squared

Secondary outcomes

1

Description

The dietary intake

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Dietary intake questionnaire

2

Description

Fasting blood glucose

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Laboratory measurement method auto analyzer

3

Description

Serum Triglyceride

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Laboratory measurement method auto analyzer

4

Description

Serum High Density Lipo protein(HDL)

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Laboratory measurement method auto analyzer

5

Description

Serum low density lipoprotein level

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Friedwalt formula

6

Description

Serum Cholestrole

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Laboratory measurement method auto analyzer

7

Description

Alanine transaminase

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Laboratory measurement method auto analyzer

8

Description

Aspartate aminotransferase

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Laboratory measurement method auto analyzer

Intervention groups

1

Description

Intervention group: each volunteer will take 2000 mg daily (one capsule 30 minutes before breakfast, two capsules 30 minutes before lunch and, one capsule 30 minutes before dinner) drug for 8 weeks. All the participants will receive a diet designed by a nutritionist. Preparation of the herbal extracts is done by basic medical sciences research center "Histogenotech" and product packaging and filling of capsules are done by Tooba Company.

Category

Treatment - Drugs

2

Description

placebo group: each volunteer will take 2000 mg daily (one capsule 30 minutes before breakfast, two capsules 30 minutes before lunch and, one capsule 30 minutes before dinner) placebo for 8 weeks. All the participants will receive a diet designed by a nutritionist.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmadieh Persian Medicine Health Center in Tehran University of Medical Sciences.

Full name of responsible person

Zahra Aghabeigloo

Street address

No. 27, Tbriz Line, North Sarparast Ave., Taleghani Ave.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8839 2558

Fax

Email

spm@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Rezaeizadeh

Street address

School of Persian Medicine, Tehran University of

Medical Sciences, SarParast St., Taleghani St., ValiAsr Blvd.

City

Tehran

Province

Tehran

Postal code

1449614353

Phone

+98 21 6697 6527

Email

rezaeizadeh@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Aghabeigloo

Position

Ph.D. candidate

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

School of Persian Medicine, Tehran University of Medical Sciences, SarParast St., Taleghani St., ValiAsr Blvd.

City

Tehran

Province

Tehran

Postal code

1449614353

Phone

+98 21 6697 6527

Email

aghabeigloo@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Aghabeigloo

Position

Ph.D. Candidate

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

School of Persian Medicine, Tehran University of Medical Sciences, SarParast St., Taleghani St., ValiAsr Blvd.

City

Tehran

Province

Tehran

Postal code

1449614353

Phone

+98 21 6697 6527

Email

aghabeigloo@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Aghabeigloo

Position

Ph.D. Candidate

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

School of Persian Medicine, Tehran University of Medical Sciences, SarParast St., Taleghani St., ValiAsr Blvd.

City

Tehran

Province

Tehran

Postal code

1449614353

Phone

+98 21 6697 6527

Email

aghabeigloo@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participants' information including questionnaires and laboratory data can be provided if additional studies are needed.

When the data will become available and for how long

For 6 months from the end of the research

To whom data/document is available

Only researchers working in academic institutions

Under which criteria data/document could be used

Having a research proposal that represents the implementation of another research project to complete the present study.

From where data/document is obtainable

Zahra Aghabeigloo

What processes are involved for a request to access data/document

Submit a request
Review of requests by researchers
Announcement of the result of the review

Comments