Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Bunium percicum 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 percicum 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 Ahmadieh 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 Brest 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 Aghabeiglooei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7725 6499

Email address

aghabeiglooei@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 percicum capsule (a Persian medicine product) on anthropometric indices and biochemical factors in overweight and obese women.

Public title
The effects of Bunium percicum 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 Brest 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 = 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 Aghabeiglooei

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

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Tehran

Province
Tehran

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1417653761

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Fax

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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.

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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 Aghabeiglooei

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.

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Zahra Aghabeiglooei

Position
Ph.D. Candidate

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Person responsible for updating data

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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 Aghabeiglooei

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