# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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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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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**Province**
Tehran

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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 Aghabeiglooei

**Position**
Ph.D. candidate

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

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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**
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**Full name of responsible person**
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**Position**
Ph.D. Candidate

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**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.

**City**
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**Province**
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aghabeiglooei@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 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**