Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Pistacia Atlantica Oleoresin of preparation on weight loss in women 18-60 years old with overweight and obesity (BMI≥25), Double-blind randomized controlled clinical trial

Protocol summary

Study aim

Evaluation of the effect of Pistacia atlantica Oleoresin of preparation on weight loss in women 18-60 years old with overweight and obesity (BMI≥25)

Design

A controlled, parallel-group, double-blind, randomized clinical trial on random selection of 60 women (aged 18-60 years/BMI over 25) referred to traditional clinic of Babol university of medical sciences after obtaining Informed consent and completing the temperament questionnaire and measuring the weight and size of the waist and hip circumference (in fasting/beginning of the day) and performing lipid profile tests after eight hours of fasting Randomly placed in two groups (drug and placebo) based on 'quadruple blocking' to use one of the medicinal forms

Settings and conduct

At first, 4 and 8 weeks after the start of treatment, the weight and size of the waist and hip circumference and their ratio in clinic of Traditional Medicine, Babol University of Medical Sciences are evaluated, and the blood lipid tests are re-checked after 8 weeks from the start of the treatment. Also, 4 weeks after the end of the treatment, weight and size around the waist and hips will be evaluated.

Participants/Inclusion and exclusion criteria

Eligibility Criteria: Patients with mild to moderate overweight and obesity (BMI between 25-39.9) Age18-60 years Exit criteria: people with a history of diabetes; cardiovascular diseases; Hepatic and renal and patients with hyperlipidemia in need of drug treatment Pregnancy and breastfeeding

Intervention groups

Intervention group: 500 mg mastic capsules two times a day (8 weeks) Control group: 500 mg starch capsules two times a day (8 weeks) People in both groups will be evaluated at the beginning of the study, at weeks 4, 8, and 12, for changes in weight, waist and hip circumference, and fat profile.

Main outcome variables

Weight, waist size, hip size, triglyceride and cholesterol levels, LDL and HDL in the blood

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221022056262N1**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Saeid Mohseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2296 7108

Email address

saeidmohseny12463@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Pistacia Atlantica Oleoresin of preparation on weight loss in women 18-60 years old with overweight and obesity (BMI≥25), Double-blind randomized controlled clinical trial

Public title
Pistacia atlantica Oleoresin of preparation on weight loss
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with mild to moderate initial overweight and obesity(BMI 25-39.9)
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization and concealment of the treatment process: Randomization is done using the method of random permutation blocks. The size of the blocks is 4 and the ratio of two groups in each block is considered equal (1:1). Medicines in two categories (drug and placebo) are prepared by the study pharmacist and sent to the study statistician. The random sequence is generated by the website https://www.sealedenvelope.com. In order to hide the treatment process, a three-digit code is considered for each drug/placebo, and three-digit codes are written on the cans containing the drug/placebo. Coding will be done by a statistician.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo will be prepared in the form of capsules completely similar to turpentine capsules (in terms of color, smell, and taste). In addition, all the capsules are placed in completely identical cans and will be provided to the study participants. Therefore, both the participants nor the evaluators of the plan are not aware of the type of treatment, so this study is double-blind. In order to match the smell, the placebo capsules are placed for some time in a space adjacent to the turpentine essential oil.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Babol University of Medical Sciences
Street address
Ganj Afrooz St
City
Babol
Province
Mazandaran
Postal code
4774547176
Approval date
2022-10-17, 1401/07/25
Ethics committee reference number
IR.MUBABOL.REC.1401.094

Health conditions studied

1

Description of health condition studied
overweight and obesity
ICD-10 code
E66.9
ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
The amount of weight change (body mass index) in overweight and obese women
Timepoint
Measurement of body mass index before the intervention, 30, 60, and 90 days after the start of the intervention
Method of measurement
Digital weighing machine

Secondary outcomes

1

Description
Measurement of the size of the abdomen
Timepoint
At the beginning of the study (before the start of the intervention), 30, 60, and 90 days after the start of intervention
Method of measurement
Measuring meter

2

Description
Blood cholesterol, triglycerides, LDL and HDL levels
Timepoint
At the beginning of the study (before the start of the intervention) and 60 days after the start of the intervention
Method of measurement
blood test

3

Description
Measure the size of the hip circumference
Timepoint
At the beginning of the study (before the start of the intervention), 30, 60, and 90 days after the start of intervention
Method of measurement
Measuring meter

4

Description
Measurement of the ratio of the size of the abdominal circumference to the size of the hip circumference
Timepoint
At the beginning of the study (before the start of the intervention), 30, 60, and 90 days after the start of intervention
Method of measurement
Measuring meter

Intervention groups

1

Description
Intervention group: Daily consumption of two 500 mg capsules of Pistacia Atlantica Oleoresin, half an hour after breakfast and dinner for 8 weeks. Pistacia Atlantica Oleoresin capsules are prepared by a pharmacy specialist in the traditional pharmacy laboratory of the Faculty of Traditional Medicine of Babol University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: Daily consumption of two placebo capsules containing 500 mg of starch, half an hour after breakfast and dinner for 8 weeks. The placebo capsule is prepared by a pharmacy specialist in the traditional pharmacy laboratory of the Faculty of Traditional Medicine of Babol University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
clinic of Traditional Medicine, Babol University of Medical Sciences
Full name of responsible person
Mrs. Dr. Narjes Gurji
Street address
Clinic Traditional Medicine of Babol, next to pardis Khodgardan College, Shahid Sargerd Ghasemi St.
City
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Mazandaran
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4717647745
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Email
info@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Mehdi Rajab Nia
Street address
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Fax
+98 11 3219 0181
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info@mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Babol 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
Babol University of Medical Sciences

Full name of responsible person
Saeid Mohseni

Position
University student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Potential sharing of all data is possible after the de-identification of individuals and upon registration of a request and approval by the institution.

When the data will become available and for how long
Access to information and data 6 months after the publication of the article is available

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, or people who are also engaged in the industry can apply to receive them.

Under which criteria data/document could be used

Having an approved proposal approved by academic institutions and also having an ethics code is mandatory to review the application.

From where data/document is obtainable

Correspondence with the e-mail of the executive in charge of the project

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

-Send the application along with documents (proposal and code of ethics) to saeidmohseny12463@gmail.com - check the request by the responsible executive and its proposal in the research council of the traditional medicine research center Answer to the request (Estimated duration of review of each request is about one month)

Comments