

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Assessing the effect of beauty slim supplement compared to placebo on weight loss in adults with obesity or overweight

Protocol summary

Study aim

Comparison of weight, BMI, fat mass, fat free mass, and waist circumference in each group and between study groups

Design

This study is a randomized controlled clinical trial with 2 groups. 80 patients will be randomly assigned into diet/placebo and diet/beautyslim.

Settings and conduct

Patients will be selected from individuals refer to Fayaz balkhsh Hospital day clinic. After assessing the inclusion criteria, information on demographic data and anthropometric measurements will be recorded. BMI will be calculated and body composition will be measured using BIA (a standard method for assessing body composition). The level of daily physical activity will be estimated using a standard physical activity questionnaire (MET) at the beginning and end of the study. Participants in both case and control groups will receive weight loss diets during the study period. To adjust the diet, after calculating the basal energy requirement individually, 500-300 calories will deduct from it and a calorie restricted diet will be given to participants. Depending on the group in which they are allocated, they will receive the supplement or placebo with the diet for 8 weeks. At the end of the 8th week, anthropometric indices will be assessed. In order to evaluate the patients' diet in terms of energy intake at the beginning and end of the study, a 3-day food recall will be completed for all patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI>23.5, age: 20-64 years, Exclusion criteria: Having chronic or acute diseases, using weight reduction medication, substance overuse, pregnancy or lactation, using oral contraceptive

Intervention groups

Supplement group: Beauty slim supplement and weight reduction diet, Placebo group: placebo and weight reduction diet

Main outcome variables

weight; fat mass; fat free mass; BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N10**

Registration date: **2021-08-04, 1400/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-04, 1400/05/13**

Update count: **0**

Registration date

2021-08-04, 1400/05/13

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Assessing the effect of beauty slim supplement compared to placebo on weight loss in adults with obesity or overweight

Public title
Beauty slim supplement and weight reduction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index>23.5 age of 20-64 years
Exclusion criteria:
Having chronic or acute illnesses Consuming weight reduction medications substance overuse pregnancy or lactation Consuming oral contraceptive

Age
From **20 years** old to **64 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization method is used to randomize the patients. For randomization, we visited the www.sealedenvelope.com and used randomization tab to make a list considering the number of intervention groups, sample size, block size (4 is selected for current study). The prepared list that contains the pattern of patient allocation was obtained and will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code at the time of sampling. The following groups of people involved in the trial: participants, Research team including principle investigator, data collectors, and outcome assessors will be blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of research and technology deputy of Shahid Beheshti University of Medical Sciences

Street address

No. 5, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1028

Health conditions studied

1

Description of health condition studied

Overweight and Obese individuals

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Weight

Timepoint

Baseline and after 2 months from the beginning of the study

Method of measurement

Scale

2

Description

Fat mass

Timepoint

Baseline and after 2 months from the beginning of the study

Method of measurement

Omron BF511 body composition scale

3

Description

Fat free mass

Timepoint

Baseline and after 2 months from the beginning of the study

Method of measurement

Omron BF511 body composition scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: calorie restricted diet + beauty slim (dried green tea and Coriander) (Sun pharmed), for two months, three capsules daily

Category

Treatment - Other

2

Description

Control group: calorie restricted diet + placebo (Sun pharmed), For two months, three capsules daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fayaz Bakhsh Hospital

Full name of responsible person

Soodeh Razeghi Jahromi

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Deputy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

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Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research and Technology Deputy, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razeghi Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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No. 7, West Arghavan St., Farahzadi Blv., Qods Town

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Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Person responsible for updating data

Contact

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Shahid Beheshti University of Medical Sciences

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data would be available to public

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

To all

Under which criteria data/document could be used

Have no other condition

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

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

sending email

Comments