Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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,

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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

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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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inquiries

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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