Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Slimtak (Combination of green tea dry extract and Cichorium intybus roots Extract) compared to placebo on weight loss in obese or overweight adults

Protocol summary

Study aim
effects of Slimtak (Combination of green tea dry extract and Cichorium intybus roots Extract) compared to placebo on weight loss in obese or overweight adults

Design
Clinical trial with placebo control group, with parallel groups, double blinded, randomized, on 80 individuals with overweight/obesity, randomization with blocks of size 4 using software

Settings and conduct
The place of the study: private clinic in Tehran; Population: people with overweight and obesity; type of blinding: double blinded; blinding, randomization and preparation of supplement cans will be done by a trained person outside the study until participants, researchers and analyzer remain blind until the end of the analysis. At the beginning and end of the intervention with supplement or placebo weight, height, BMI, and body composition will be measured. Participants in both groups will receive weight loss diets based intervention with supplement/placebo during the study period. Study duration will be 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: BMI:25-40, age: 18-65 years, and willing to participate in the study. Exclusion criteria: Using weight reduction medication, substance overuse, pregnancy or lactation, having known kidney disease, and having known heart disease

Intervention groups
Supplement group: 3 Slimtak capsule with each meal and weight reduction diet, Placebo group: 2 placebo capsules with each meal and weight reduction diet for 8 weeks

Main outcome variables
weight; fat mass; fat free mass; BMI

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140804018677N25**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **prospective**

Last update: **2023-03-29, 1402/01/09**
Update count: **0**

Registration date
2023-03-29, 1402/01/09

Registrant information

Name
soodeh razeghi Jahromi

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 6634 8500

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razeghi@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-03, 1402/01/14

Expected recruitment end date
2023-09-05, 1402/06/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effects of Slimtak (Combination of green tea dry extract and Cichorium intybus roots Extract) compared to placebo on weight loss in obese or overweight adults

Public title
Effects of Slimtak (Combination of green tea dry extract and Cichorium intybus roots Extract) on weight loss in obese or overweight adults

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Body mass index of 25-40 age of 16-65years Willing to participate

Exclusion criteria:
Consuming weight reduction medications substance overuse Pregnancy and lactation Having known kidney disease Having known heart disease

Age
From **18 years** old to **65 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
Participants in the study are selected by convenience sampling method. Patients are classified according to age and gender, and each person will be placed in a group receiving supplementation or placebo using 1:1, quadruple random blocks. Quadruple blocks are randomly designed through software such as ..... (ABAB), (BBAB), (AABB), (ABBA), (BAAB). Assigning A or B to the supplement or placebo group will be done by someone outside the research so that the researchers remain blind. According to the list of randomly prepared quadruple blocks, a trained person outside the research team is responsible for randomly assigning patients. After each patient enters, according to the quadruple blocks prepared in the first stage, each patient is randomly assigned to group A or B. Assignment process will be done consecutively until the sampling is completed.

Blinding (investigator's opinion)
Double blinded

Blinding description
It is a double blind study. Participants, research team including principle investigator, data collectors, and outcome assessors will be blind to supplement or placebo allocation. Blinding would be performed by a third person out of study team. Allocation data would be unavailable to study team till the end of data collection and analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committees of National Nutrition & Food Technology Research Institute

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

City
Tehran

Province
Tehran

Postal code
1981619573

Approval date
2023-01-22, 1401/11/02

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.069

Health conditions studied

1

Description of health condition studied
Overweight and Obesity

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: The duration of intervention in this clinical trial will be 8 weeks. Beside calorie restricted diet (300-500 Kcal less than calculated daily energy need) people will receive 3 capsules of Slimtack (each capsules contains 200 mg green tea dry extract and 80 mg Cichorium intybus roots Extract) (Takin Pars pharmed company) with each meal.

Category

Treatment - Other

2

Description

Control group: The duration of intervention in this clinical trial will be 8 weeks. Beside calorie restricted diet (300-500 Kcal less than calculated daily energy need) people will receive 3 capsoules of placebo (each capsouls contains 500 mg corn starch) (Takin Pars pharmed company) with each meal.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic

Full name of responsible person

Soodeh Razeghi Jahromi

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

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soodehrazeghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Takin Pars pharmed Company

Full name of responsible person

ساحل رحیمی

Street address

Zagros Building, No. 37, 1st East Boostan, Farahzadi Boulevard, Shahrak-e Qods, Tehran, Iran

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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

Takin Pars pharmed Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general 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

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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences
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Position
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Other areas of specialty/work
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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
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Coded data of the participants, study protocol, and report of the main output of the study would be available in case of researchers' reasonable request sending to principal investigator of the study 6 months after publishing the article.
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
University researchers
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