

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effects of slimming topical gel on anthropometric indices and body composition and biochemical factors in overweight and obese women: A double blind randomized controlled trial

Protocol summary

Study aim

The effects of slimming topical gel on anthropometric indices and body composition and biochemical factors in overweight and obese women: A randomized controlled study

Design

The study will be conducted on 30 obese and overweight women.

Settings and conduct

The study will be conducted at the Nutrition Research Center of Tabriz University of Medical Sciences and the duration of using slimming gel will be 8 weeks. The topical gels of the intervention and placebo groups will be coded by the person responsible for preparation, and the main researchers and patients will be blinded to the type of supplement consumed in each group.

Participants/Inclusion and exclusion criteria

inclusion criteria: women ,19-65 years old body mass index above30 or above 27 with one or two risk factors like hypertension and type 2 diabetes. exclusion criteria:consumption of weight loss drugs and supplements three months before the intervention Hypothyroidism heart disease Taking high-dose oral corticosteroids Pregnant and lactating women Smoking and alcohol consumption

Intervention groups

3 groups of 10 people 1) topical use of gel Slimming for the entire abdominal circumference 2) Using slimming gel for half the abdominal circumference 3) Using Oserin as a placebo for the abdominal circumference

Main outcome variables

Anthropometric indices (Weight, Height, BMI, Waist circumference, Hip circumference, Waist to Hip Ratio)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090609002017N37**

Registration date: **2023-06-14, 1402/03/24**

Registration timing: **prospective**

Last update: **2023-06-14, 1402/03/24**

Update count: **0**

Registration date

2023-06-14, 1402/03/24

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of slimming topical gel on anthropometric indices and body composition and biochemical factors in overweight and obese women: A double blind randomized controlled trial

Public title
The effects of slimming topical gel on overweight and obese women

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 19-65 years old body mass index above 30 or above 27 with one or two risk factors like hypertension and type 2 diabetes
Exclusion criteria:
 consumption of weight loss drugs and supplements three months before the intervention Hypothyroidism heart disease Taking high-dose oral corticosteroids Pregnant and lactating women Smoking and alcohol consumption

Age
From **19 years** old to **65 years** old

Gender
Female

Phase
1-2

Groups that have been masked

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

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
 participants randomly using random block method and RAS (Random Allocation Software) and allocation ratio 1:1:1 and after equalization based on body mass index into 3 groups of 10 people 1) topical use of gel Slimming for the entire abdominal circumference 2) Using slimming gel for half the abdominal circumference 3) Using Oserin as a placebo for the abdominal circumference for 8 weeks

Blinding (investigator's opinion)
Double blinded

Blinding description
 For all three study groups, the topical gel used will be the same in terms of shape, color and dosage. Participants, the principal investigator, health care personnel, those evaluating the outcome, the Data Safety and Monitoring Committee, and those drafting the article will be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Golgasht St

City

tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TBZMED.REC.1402.119

Health conditions studied

1

Description of health condition studied

obesity and overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Antropometric indices (Weight, Height, BMI, Waist circumference, Hip circumference, Waist to Hip Ratio)

Timepoint

Baseline and at the end of intervention

Method of measurement

Physical exam

Secondary outcomes

1

Description

body composition

Timepoint

baseline and after intervention

Method of measurement

tanita body composition analysis device

2

Description

Liver enzymes, BUN and creatinine

Timepoint

baseline and after intervention

Method of measurement

biochemical methods

3

Description

appetite

Timepoint

baseline and after intervention

Method of measurement

visual analog scale appetite

Intervention groups

1

Description

Intervention group: The intervention group will apply the topical jell every day for 8 weeks. The instruction to use the ointment will be applying 1 cc to the whole abdominal area except around the belly button (i.e., 10 cm²) and to cover the area with a plastic sheet.

Category

Treatment - Drugs

2

Description

Intervention group: The intervention group will apply the topical jell every day for 8 weeks. The instruction to use the ointment will be applying 1 cc to the half of the abdominal area except around the belly button (i.e., 10 cm²) and to cover the area with a plastic sheet.

Category

Treatment - Drugs

3

Description

placebo group: The placebo group will apply the topical oserin every day for 8 weeks. The instruction to use the ointment will be applying 1 cc to the half of the abdominal area except around the belly button (i.e., 10 cm²) and to cover the area with a plastic sheet.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Research Center

Full name of responsible person

Dr.Alireza Ostadrahimi

Street address

Nutrition Research Center, Tabriz University of Medical Sciences; Attar Neishabouri Avenue, Golgasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Position

Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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

Undecided - It is not yet known if there will be 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

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

Data will be available 12 months after manuscript publication

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta-analysis.

From where data/document is obtainable

The researchers (student and her supervisor)

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

Request a document via email

Comments