

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

ostadrahimi@tbzmed.ac.ir

##### 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 cm<sup>2</sup>) 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 cm<sup>2</sup>) 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 cm<sup>2</sup>) 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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

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##### **Phone**

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##### **Email**

ostadrahimi@tbzmed.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr.Parviz SHahabi

##### **Street address**

Tabriz University of Medical Sciences, Attar Neishabouri Street, Golgasht Avenue

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##### **Email**

parvizshahabi@gmail.com

#### **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

**Name of organization / entity**  
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Dr. Alireza Ostadrahimi  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr.Samira Pourmoradian  
**Position**

Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
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pourmoradians@tbzmed.ac.ir

## 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