

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### **Effect of ginger (*zingiber officinale* Roscoe) supplementation on nutritional status and circulating levels of some adipocytokines in obese women with regard to genetic polymorphism of UCP-1, leptin, adiponectin and beta 3 adrenergic receptors**

#### **Protocol summary**

##### **Summary**

(1) Objectives: Effect of ginger (*zingiber officinale* Roscoe) supplementation on nutritional status and circulating levels of some adipocytokines in obese women with regard to genetic polymorphism of UCP-1, leptin, adiponectin and beta 3 adrenergic receptors. (2) Design: Double blind randomized clinical trial. (3) Setting and conduct: 80 eligible obese women which meet the inclusion criteria during a general call will be selected and randomly divided into two groups: intervention (ginger) and control (placebo). (4) Participants including major eligibility criteria: Obese volunteer women ( $30 \leq \text{BMI} \leq 40$ ) in the age group 18-48 years without any exclusion criteria including: Pregnancy; Lactation; Menopause; Being under weight loss diets at now or in the past 3 months; Vigorous physical activity; History of diabetes; Cardio-vascular disease; Hypo or hyperthyroidism; Gall stones; Deep depression; Constantly use of medications such as Propranolol or other beta-blockers, Warfarin, Corticosteroids; Any history of allergy to ginger; Constantly taking vitamin supplements or ginger at now or in the past 3 months; Smoking. (5) Intervention: intervention group (receiving 2 grams per day of powdered ginger as 2 tablets, before meals for 3 months) and control group (receiving 2 g corn starch as 2 placebo tablets, before meals for 3 months). (6) Main outcome measures: Anthropometric measurements (weight, BMI, waist and hip circumference) ; Body composition; Appetite; Energy and nutrient intake; Determining genetic polymorphism of UCP-1, leptin, adiponectin and beta 3 adrenergic receptors genes; Serum levels of leptin, adiponectin and resistin ;Serum levels of total antioxidants and malondialdehyde.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT201311172017N18**

Registration date: **2014-01-22, 1392/11/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

2014-01-22, 1392/11/02

##### **Registrant information**

##### **Name**

Alireza Ostadrahimi

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

Tabriz University of Medical Sciences

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

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##### **Email address**

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##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

Nutrition Research Center, Tabriz University of Medical Science

##### **Expected recruitment start date**

2013-09-23, 1392/07/01

##### **Expected recruitment end date**

2013-12-21, 1392/09/30

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty  
**Trial completion date**  
empty

**Scientific title**  
Effect of ginger (zingiber officinale Roscoe) supplementation on nutritional status and circulating levels of some adipocytokines in obese women with regard to genetic polymorphism of UCP-1, leptin, adiponectin and beta 3 adrenergic receptors

**Public title**  
Effect of ginger (zingiber officinale Roscoe) supplementation on nutritional status and circulating levels of some adipocytokines in obese women

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria were: Obese women ( $30 \leq \text{BMI} \leq 40$ ) in the age group 18-48 years. Exclusion criteria were: Aged under 18 or over 48; Pregnancy; Lactation; Menopause; Being under weight loss diets at now or in the past 3 months; Vigorous physical activity; History of diabetes; Cardio-vascular disease; Hypo or hyperthyroidism; Gall stones; Deep depression; Constantly use of medications such as propranolol or other beta-blockers, warfarin, corticosteroids; Any history of allergy to ginger; Constantly taking vitamin supplements or ginger at now or in the past 3 months; Smoking.

**Age**  
From **18 years** old to **48 years** old

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
Randomization is performed by permuted block randomization (block size: 4) using RAS software.

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Tabriz University of Medical Sciences  
**Street address**  
Golgasht street- Tabriz University of Medical Sciences  
**City**  
Tabriz  
**Postal code**  
**Approval date**  
2013-12-19, 1392/09/28  
**Ethics committee reference number**  
92154

## Health conditions studied

1

**Description of health condition studied**

obesity

**ICD-10 code**

E66.0

**ICD-10 code description**

Obesity due to excess calories

## Primary outcomes

1

**Description**

Anthropometric measurements

**Timepoint**

4 times during the study: at the beginning and end of each intervention month

**Method of measurement**

Anthropometric measurements including weight using calibrated Seca scale with a precision of 0.1 kg and a minimum of clothes in the morning, height, waist and hip circumference using a tape measure with an accuracy of 0.1 cm, and BMI and waist-hip ratio was calculated.

2

**Description**

Body composition

**Timepoint**

4 times during the study: at the beginning and end of each intervention month

**Method of measurement**

Measurement of body composition, including fat mass, fat free mass and total body water determination using Bioelectric Impedance Analyzer ( BIA).

3

**Description**

Appetite

**Timepoint**

4 times during the study: at the beginning and end of each intervention month

**Method of measurement**

using 5 items questionair based on the VAS scale

#### 4

**Description**

Energy and nutrient intake

**Timepoint**

3 times; at first, midst and the end of intervention

**Method of measurement**

3 days food record was used and analyzed with Nutritionist 4 software

#### 5

**Description**

Serum levels of leptin, adiponectin and resistin

**Timepoint**

Before and after intervention

**Method of measurement**

By Laboratory ELISA Kits

#### 6

**Description**

Serum levels of total antioxidants and Malondialdehyde

**Timepoint**

Before and after intervention

**Method of measurement**

TAC: Enzymatic method by commercial kits; MDA: Reaction with thiobarbituric acid by fluorimetry method

#### 7

**Description**

Determining genetic polymorphism of UCP-1, leptin, adiponectin and beta 3 adrenergic receptors genes

**Timepoint**

At first- as a independent variable

**Method of measurement**

RFLP-PCR

### Secondary outcomes

#### 1

**Description**

Fasting blood sugar

**Timepoint**

Before and after intervention

**Method of measurement**

Enzymatic method

#### 2

**Description**

Serum level of Insulin

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

#### 3

**Description**

Serum Lipid profile

**Timepoint**

Before and after intervention

**Method of measurement**

Enzymatic method for total cholesterol, triglyceride and HDL.cand Freidwald's formula for LDL.c

### Intervention groups

#### 1

**Description**

Intervention group: 2 grams powdered dry ginger as 2 tablets per day for 90 day

**Category**

Treatment - Drugs

#### 2

**Description**

Control group: 2 grams powdered corn starch as 2 tablets per day for 90 day

**Category**

Placebo

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Faculty of Nutrition, Tabriz University of Medical Sciences

**Full name of responsible person**

Vahideh Ebrahimzadeh Attari

**Street address**

Faculty of Nutrition, Tabriz University of Medical Sciences

**City**

Tabriz

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Nutrition Research Center, Tabriz University of Medical Science

**Full name of responsible person**

Dr. Alireza Ostadrahimi

**Street address**

Golgasht Street, Attar neishaboori Avenue, Nutrition Research Center, Tabriz University of Medical Sciences

**City**

Tabriz

**Grant name**

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**Grant code / Reference number**

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

Yes

**Title of funding source**

Nutrition Research Center, Tabriz University of Medical Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*