Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ≤ BMI ≤ 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

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Alireza Ostadrahimi
Name of organization / entity
Tabriz University of Medical Sciences
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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 ≤ BMI ≤ 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 questionnair 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 dayes food record was used and analyzed with Nutritionist 4 software

5

Description
Serum levels of leptin, adiponectin and resistin
Timepoint
Befor 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 suger
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutrition Research Center, Tabriz Univercity of Medical Science
Full name of responsible person
Dr. Alireza Ostadrahimi
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Golgasht Street, Attar neishaboori Avenue, Nutrition Research Center, Tabriz University of Medical Sciences
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Tabriz
Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nutrition Research Center, Tabriz Univercity 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

Faculty of Nutrition, Tabriz University Of Medical Sciences

Full name of responsible person

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Position

Ph.D Student of Nutrition

Other areas of specialty/work

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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