

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The Effect of Ginger supplementation and high intensity Interval Training on metabolic status, serum irisin and anthropometric indices in obese men

Protocol summary

Study aim

Determining the effect of ginger supplement and high intensity interval training on metabolic status, serum irisin and anthropometric indices in obese men

Design

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables.

Settings and conduct

In this study, samples from obese men aged 20 to 35 are selected by public call in different places. The participants will be those who are not already under any specialist diet program, etc. Therefore, people who are not currently willing to receive a diet are enrolled in the study. The company will be volunteers. At the beginning of the study, the objectives will be fully explained to the participants and written consent will be obtained. After explaining the conditions of the study, those who were willing to participate in the study, and also had criteria for entry, were selected and will be included in the study for 10 weeks. They will then be informed of the written consent form of the company and will be assured in order to preserve the information and to make the cooperation optional. Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male gender Desire to cooperate and sign a informed consent form after full knowledge of the goals and method of carrying out the study Age group 20 to 35 years old BMI kg / m ² 40-30 Exit criteria: Follow

certain diets in the last 6 months Using drugs (glucose, statins, glucocorticoids ...) or other food supplements Participate in any regular sports activities smoking Food allergy People with diabetes, cardiovascular disease, respiratory disease, hyperthyroidism or hypothyroidism, kidney liver disease, digestive disease or other illnesses.

Intervention groups

Intervention group: Recipe daily 3 g ginger (three capsules of 1 g) Intervention group: Ginger plus to HIIT Exercise (daily 3g ginger is as three capsules of 1 gram and HIIT exercise for 10 weeks a week, 3 sessions and a total of 30 sessions) Intervention group: Practice HIIT plus to Placebo (3 g starch daily in the form of three capsules of 1 g and a HIIT exercise for 3 weeks each week and a total of 30 sessions per week) Control group: Placebo (3 g starch per day, 3 capsules per gram)

Main outcome variables

The results of this study can be helpful in providing appropriate strategies for controlling obesity and metabolic complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100408003664N20**

Registration date: **2018-03-20, 1396/12/29**

Registration timing: **prospective**

Last update: **2018-03-20, 1396/12/29**

Update count: **0**

Registration date

2018-03-20, 1396/12/29

Registrant information

Name

Maryam Rafrat

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1335 7580

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Ginger supplementation and high intensity Interval Training on metabolic status, serum irisin and anthropometric indices in obese men

Public title

The Effect of Ginger supplementation and high intensity Interval Training on metabolic status, serum irisin and anthropometric indices in obese men

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Male gender Desire to cooperate and sign a informed consent form after full knowledge of the goals and method of carrying out the study Age group 20 to 35 years old BMI 30-40 kg/m²

Exclusion criteria:

Follow certain diets in the last 6 months use of drugs glucose lowering agent, statins, glucocorticoids ... or food supplements Participate in any regular sports activities Smoking Food allergies People with diabetes, cardiovascular disease, respiratory disease, hyperthyroidism or hypothyroidism, kidney liver disease, digestive disease or other illnesses

Age

From 20 years old to 35 years old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables.

Blinding (investigator's opinion)

Double blinded

Blinding description

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to age and BMI variables

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 Science

Street address

Tabriz University of Medical Science, Attar Neishabouri Avenue, Golgasht street, Tabriz

City

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Province

East Azarbaijan

Postal code

5138663134

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.TBZMED.REC.1396.1096

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Total Cholesterol

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Enzymatic method

2

Description

Triglyceride

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Enzymatic method

3

Description

HDL-C

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Enzymatic method

4

Description

LDL-C

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Formula

5

Description

Glucose

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Enzymatic method

6

Description

Insulin

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

ELISA

7

Description

HOMA-IR

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Formula

8

Description

Irisin

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

ELYSA

9

Description

Anthropometric Indicators

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Metre

Secondary outcomes

1

Description

Diet

Timepoint

Before the intervention, 5 weeks after it and 10 weeks after its start

Method of measurement

3-day food record

2

Description

Physical activity

Timepoint

Before the intervention and 10 weeks after starting

Method of measurement

Before the intervention and 10 weeks after it begins

Intervention groups

1

Description

Intervention group: Recipe daily 3 g ginger (three capsules of 1 g)

Category

Treatment - Other

2

Description

Intervention group: Ginger plus to HIIT Exercise (daily 3 g ginger is as three capsules of 1 gram and HIIT exercise for 10 weeks a week, 3 sessions and a total of 30 sessions)

Category

Treatment - Other

3

Description

Intervention group: Practice HIIT plus to Placebo (3 g starch daily in the form of three capsules of 1 g and a HIIT exercise for 3 weeks each week and a total of 30 sessions per week)

Category

Treatment - Other

4**Description**

Control group: Placebo (3 g starch per day, 3 capsules per gram)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Student dormitories

Full name of responsible person

Mohammad bakhshi

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Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Nutritional Reseach Center of 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

Nutritional Reseach Center of 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

Mohammad bakhshi

Position

MS student in Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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