

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of high intensity interval training and ginger supplement on serum levels of soluble intracellular adhesion molecule type 1, monocyte chemotactic protein type 1, and interleukine 10 in overweight women

Protocol summary

Summary

This is a quasi-experimental, randomized, placebo controlled study. It aims to examine the effects of ginger supplement and high intensity interval training on serum levels of soluble intracellular adhesion molecule type 1, monocyte chemotactic protein type 1, and interleukine 10 in overweight women. Twenty-four healthy women who meet inclusion criteria (age between 20 to 30 years; body mass index between 25 to 29.9 kilogram/squared meter) will be randomly allocated into 3 groups. They involve ginger (n=8), train+ginger (n=8), and train+placebo (n=8). The groups will perform high intensity interval training for 10 weeks (40 meter maximal shuttle run, from 8 to 10 a.m.) and ginger consumption (3 gram of Vomigan Ginger tablet produced in Dineh Company, Iran, 1 gram before each meal with a glass of water) or placebo (3 gram of Gram Flour tablets produced in Dineh Company, Iran, 1 gram before each meal with a glass of water) on a daily basis. Effects of the interventions will be studied on soluble intracellular adhesion molecule type 1, monocyte chemotactic protein type 1, and interleukine 10 as primary outcome variables and on blood pressure, body fat percentage, Vo2max, cardiac structural and functional variables, and lipid profile as secondary outcome variables. Exclusion criteria include cardiovascular and respiratory problems; diabetes; high blood pressure; orthopaedic diseases; smoking; pregnancy; performance of regular exercise training during last year; and menstrual disorder.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051027836N1**

Registration date: **2016-06-18, 1395/03/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Shila Nayeibifar

Name of organization / entity

Birjand University

Country

Iran (Islamic Republic of)

Phone

+98 56 3223 8192

Email address

shila_neyebi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2016-07-30, 1395/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of high intensity interval training and ginger supplement on serum levels of soluble intracellular adhesion molecule type 1, monocyte chemotactic protein type 1, and interleukine 10 in overweight women

Public title

Effects of exercise training and herbal medicine on inflammatory markers

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Women aged between 20 to 30 years; having body mass index between 25 to 29.9 kilogram/squared meter Exclusion criteria: Having cardiovascular and respiratory problems; diabetes; high blood pressure; orthopedic diseases; smoking; pregnancy; regular exercise training during last year; having menstrual disorder

Age
From **20 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences

Street address
Ghaffari Street

City
Birjand

Postal code
9717853577

Approval date
2016-06-12, 1395/03/23

Ethics committee reference number
IR.BUMS.1395.28

Health conditions studied

1

Description of health condition studied

Overweight
ICD-10 code
E66.9
ICD-10 code description
Simple obesity NOS

Primary outcomes

1

Description
Interlukine 10

Timepoint
24 hours before the first session and 48 hours after the last training session at the end of 10 weeks of intervention

Method of measurement
Serum Blood Sampling, Special Kits

2

Description
Soluble Interacellular Adhesion Molecule type 1

Timepoint
Twenty four hours before the first training session and forty eight hours after the last training session at the end of 10 weeks of intervention

Method of measurement
Serum Blood Sampling, Special Kits

3

Description
Monocyte Chemotactic Protein type 1

Timepoint
Twenty four hours before the first training session and forty eight hours after the last training session at the end of 10 weeks of intervention

Method of measurement
Serum Blood Sampling, Special Kits

Secondary outcomes

1

Description
Blood Pressure

Timepoint
Twenty four hours before the first training session and forty eight hours after last trainnig session at the end of 10 weeks of intervantion

Method of measurement
Rishter Blood Pressure Barometer, milimeter Hg

2

Description
Body Fat Percentage

Timepoint
Twenty four hours before the first training session and forty eight hours after last trainnig session at the end of 10 weeks of intervantion

Method of measurement

Yagami Caliper made in Japan

3

Description

Vo2max (Maximal Oxygen Consumption)

Timepoint

Twenty four hours before the first training session and forty eight hours after last training session at the end of 10 weeks of intervention

Method of measurement

Bruce test on treadmill

4

Description

Cardiac structural and functional variables

Timepoint

Twenty four hours before the first training session and forty eight hours after last training session at the end of 10 weeks of intervention

Method of measurement

Heart Echocardiographic System

5

Description

Lipid Profile

Timepoint

Twenty four hours before the first training session and forty eight hours after last training session at the end of 10 weeks of intervention

Method of measurement

Serum Blood Sampling

Intervention groups

1

Description

Train + Placebo Intervention Group: Doing high intensity interval training (40 meters maximal shuttle run, 4 repetitions in the first week and 8 repetitions in the 10th week, together with daily intake of gram flour placebo tablets produced in Dineh Company, Iran, 1 gram before each meal with 1 glass of water for 10 weeks)

Category

Prevention

2

Description

Ginger + Train Intervention group: Doing high intensity interval training (40 meters maximal shuttle run, 4 repetitions in the first week to 10 repetitions in the 10th week, together with daily intake of Vomigan ginger tablets produced in Dineh Company, Iran, 1 gram before each meal with 1 glass of water for 10 weeks)

Category

Prevention

3

Description

Ginger Group: Daily intake of 3 grams of Vomigan Ginger tablet produced in Dineh Company, Iran, 1 gram before each meal with 1 glass of water for 10 weeks without doing physical training

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand University

Full name of responsible person

Shila Nayeibifar

Street address

Birjand University, Shokat Abad

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Shila Nayeibifar

Street address

50 P, Moallem 11, Moallem Street, Birjand, Iran

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Birjand University

Full name of responsible person

Shila Nayeibifar

Position

Phd Student of Exercise Physiology

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