

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of combined administration of weight reducing diet and apple cider vinegar on anthropometric indices and serum lipids, glucose and neuropeptide Y levels in obese patients

Protocol summary

Summary

Method of this study has designed based on Randomized Clinical Trial principles. The goal of this study is the Effect of combined administration of weight reducing diet and apple cider vinegar on anthropometric indices and serum lipids, glucose and neuropeptide Y levels in obese patients. In this study cases were chosen from obese patients (BMI ≥ 27 kg/m²) with no exclusion criteria. After completing informed consent form, obese patients will be requested to be fast for 12 to 14 hours in subsequent presence. Then we will catch 5 cc venous blood from patients and they will be weighed with 100 grams precision and light clothing and will be calculated their stature without shoes with 0.5 cm precision and waist circumference and bioelectrical impedance analysis and their general characteristic will be record in data collecting sheet. Then cases will be divided to two groups. One group (case group) will be received combined administration of weight reducing diet and apple cider vinegar and the other group (control group) will be received only weight reducing diet. Obese patients in case group will consume 30 cc apple cider vinegar daily (15 cc with lunch and 15 cc with dinner) during 12 weeks, while obese patients in control group will be recommended to consumption of any kinds of vinegar specially apple cider vinegar. At the end of sixth week of study, in all patients anthropometric indices, weight, waist circumference and body fat composition will be again calculated. At the end of the twelfth week, 5 cc blood after 12 to 14 hours fasting will be again catch from patients and anthropometric indices (weight, waist circumference and body fat composition) will be again recorded. Finally blood samples will be centrifuge for 15 minutes at 2000 rpm to separating serum component. Then serum NPY and HDL-C, LDL-C, TC, TG density and FBS will be measured with ELISA method by Japanese kit and enzymatic method by Iranian kit

respectively. In this study sample size according to standard deviation (SD) of previous studies and equality of variance in two groups based on formula for each group has calculated 22 patients that because of probable infusion, 25 patients in each group has considered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122815968N1**

Registration date: **2014-03-10, 1392/12/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-10, 1392/12/19

Registrant information

Name

Atoosa Saidpour

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
School of nutrition

Country

Iran (Islamic Republic of)

Phone

-

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research
Institute

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combined administration of weight reducing diet and apple cider vinegar on anthropometric indices and serum lipids, glucose and neuropeptide Y levels in obese patients

Public title

Effect of combined administration of weight reducing diet and apple cider vinegar in obese patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:tendency to cooperation- Body mass index more than 27 kg/m² - age limitation of 20 to 60 years old Exclusion criteria: hypothyroidism and diabetes mellitus -digestive diseases- consumption of effective drugs to weight changes(such as sibutramine, xenical,glucocorticoid hormones, antipsychotic and antidepressant drugs),consumption of nutritional supplements with title of weight reducing (such as green tea)- pregnancy and lactation- allergy to apple cider vinegar

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Nutrition and Food Technology Research Institute

Street address

Tehran,qods(qarb) town, shahid farahzadi boulevard,shahid hafezi street (west arqavan),7 tag

City

Tehran

Postal code

1981619573

Approval date

2013-12-08, 1392/09/17

Ethics committee reference number

92/4983/پ

Health conditions studied**1****Description of health condition studied**

obesity

ICD-10 code

E65, E66

ICD-10 code description

Localized adiposity, Obesity

Primary outcomes**1****Description**

waist circumference

Timepoint

before intervention, six weeks after intervention,twelve weeks after intervention

Method of measurement

meter

2**Description**

weight

Timepoint

before intervention, six weeks after intervention,twelve weeks after intervention

Method of measurement

scale

3**Description**

Body Mass Index

Timepoint

before intervention, six weeks after intervention,twelve weeks after intervention

Method of measurement

calculating

4

Description

Body Fat Composition

Timepoint

before intervention, six weeks after intervention, twelve weeks after intervention

Method of measurement

Bioelectrical Impedance Analysis

Secondary outcomes

1

Description

serum NPY Neurotransmitter

Timepoint

before intervention, twelve weeks after intervention

Method of measurement

ELISA method

2

Description

serum lipids density

Timepoint

before intervention, twelve weeks after intervention

Method of measurement

Enzymatic method by kit

3

Description

Fasting Blood Sugar

Timepoint

before intervention, twelve weeks after intervention

Method of measurement

Enzymatic method by kit

Intervention groups

1

Description

patients in apple cider vinegar group (intervention group) will receive 30 cc apple cider vinegar (15 cc with lunch and 15 cc with dinner) during 12 weeks.

Category

Other

2

Description

control group: without action (placebo)

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Clinical Nutrition and Diet Therapy Clinic of Shahid Beheshti university of medical sciences

Full name of responsible person

Solaleh Sadat Khezri, MS student of nutritional sciences

Street address

Tehran, qods(qarb) town, shahid farahzadi boulevard, shahid hafezi street, baran street

City

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr. Fatemeh Mohammadi Nasrabadi

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Tehran, qods(qarb) town, shahid farahzadi boulevard, shahid hafezi (west arqavan) street, 7 tag

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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

National Nutrition and Food Technology Research Institute

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**

National Nutrition and Food Technology Research Institute

Full name of responsible person

Solaleh Sadat Khezri

Position

MS Student of Nutrition

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti university of medical sciences-
school of nutrition

Full name of responsible person

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Position

PHD 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