Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 santrifuge for15 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 antidepression 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
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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
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Solaleh Sadat Khezri
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Person responsible for scientific inquiries

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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