Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of apple cider vinegar tablets on metabolic syndrome and its components in patients with metabolic syndrome

Protocol summary

Summary

The aim of this study is evaluation the effect of apple vinegar tablets on metabolic syndrome and its components in 20 to 60 years old patients with metabolic syndrome. Pregnant and lactating women, drug addicts and people with underlying disease will be excluded. 120 people will be randomly divided into two groups: 60 in apple cider vinegar tablets group and 60 in placebo group. Tablets will be consumed twice a day, after lunch and dinner for three months. Factors affecting the metabolic syndrome, including type and amount of diet and physical activity will be at the same level. Based on ATPIII criteria three or more of the following criteria is enough for diagnosis of metabolic syndrome in the Middle East: Central obesity (Waist circumference in men> cm94 and women> cm80) hypertriglyceridemia: (TG> mg/dl 150 or treated with anti-lipid) Low levels of HDL-C: Men <mg/dl 40 and in women <mg/dl 50 or treated with anti-lipid) Hypertension: systolic blood pressure>130 or diastolic>85 or antihypertensive therapy) High blood glucose>mg/dl 100 or by treatment with a previous diagnosis of DM2 All diagnostic criteria intervention in both groups before and after the intervention will be measured and recorded. Finally, the two groups will be compared.

General information

Acronym

ACV , apple cider vinegar

IRCT registration information

IRCT registration number: **IRCT2015051222232N1**
Registration date: **2015-06-02, 1394/03/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-06-02, 1394/03/12

Registrant information

Name
Marzieh Peyravi Dehsorkhi

Name of organization / entity
Ardabil University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 45 3351 2006

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h.doustkami@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2015-06-05, 1394/03/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of apple cider vinegar tablets on metabolic syndrome and its components in patients with metabolic syndrome

Public title

The effect of apple cider vinegar tablets on metabolic syndrome and its components in patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with metabolic syndrome twenty to sixty years old Exclusion criteria: Pregnant patients; nursing mothers; smokers; consumers of alcohol; drugs; patients with type I diabetes; significant impairment of renal function; thyroid disorders; liver disorders; acute and chronic inflammatory diseases; lack of mobility; recent surgery; myocardial infarction; any cerebrovascular accident in the last quarter

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ardabil University of Medical Sciences

Street address
Ardabil University of Medical Sciences, Daneshgah st., Ardabil,

City
Ardabil

Postal code
56189985991

Approval date
2014-10-18, 1393/07/26

Ethics committee reference number
arums.ric.93.50

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
high blood pressure

2

Description of health condition studied
Central obesity

ICD-10 code
E65

ICD-10 code description
Localized adiposity

3

Description of health condition studied
High density lipoprotein deficiency

ICD-10 code
E78.6

ICD-10 code description
High density lipoprotein deficiency

4

Description of health condition studied
hypertriglyceridaemia

ICD-10 code
E78.1

ICD-10 code description
hypertriglyceridaemia

5

Description of health condition studied
High blood Glucose

ICD-10 code
R73.9

ICD-10 code description
Hyperglycemia, unspecified

Primary outcomes

1

Description
Metabolic syndrome

Timepoint
Before the intervention and after three months of intervention

Method of measurement
According to criteria of ATPIII three or more of the following criteria for diagnosis of metabolic syndrome is in the Middle East: Central obesity (waist circumference in men> cm 94 in women> cm 80) hypertriglyceridemia (TG> mg / dl 150 or anti-lipid therapy), low levels of HDL-C: Men <mg / dl 40 and in women <mg / dl 50 or anti-lipid therapy) hypertension (systolic blood pressure> 130 or diastolic> 85 or under antihypertensive treatment), high blood sugar> mg / dl 100 or by treatment with a previous diagnosis DM2

Secondary outcomes

1

Description
FBS
Timepoint
Before the intervention and three months after intervention
Method of measurement
In milligrams per deciliter of blood samples will be measured by standard devices; BT-3500 made in Italy and OLYMPUS AU400 models made in Japan

2

Description
triglyceride
Timepoint
Before the intervention and three months after intervention
Method of measurement
In milligrams per deciliter of blood samples will be measured by standard devices; BT-3500 made in Italy and OLYMPUS AU400 models made in Japan

3

Description
high density lipoprotein- Cholesterol
Timepoint
Before the intervention and three months after intervention
Method of measurement
In milligrams per deciliter of blood samples will be measured by standard devices; BT-3500 made in Italy and OLYMPUS AU400 models made in Japan

4

Description
waist circumference
Timepoint
Before the intervention and three months after intervention
Method of measurement
In cm by means of meters and when standing at the level of the umbilicus (between vertebrae L4 and L5) is measured.

5

Description
Blood pressure
Timepoint
Before the intervention and three months after intervention
Method of measurement
Will be in millimeters of mercury. Mercury barometer by Richter and by calculating the average of 3 times measured in a sitting position and after ten minutes of rest will be measured. Diastolic blood pressure was measured using the fifth korotokof sound.

Intervention groups

1

Description
Intervention group of apple cider vinegar tablets containing 400 to 500 milligrams of active ingredient of apple vinegar Manufactured with American Bronson company twice a day after lunch and dinner will be given for three months.
Category
Treatment - Drugs

2

Description
The control group received placebo pills (placebo) with the same dimensions of the original drug (apple vinegar tablets) will be. And will have no pharmacological effect. Twice a day, immediately after lunch and dinner and will be given a period of three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
The office of the doctor, Mahmoud Parham
Full name of responsible person
Dr. Mahmoud Parham, Professor of Endocrinology and Metabolism, faculty member Qom University
Street address
Qom, 45-meter street Saduq Street Shahbazi, Medical Building, third floor, the office of the doctor Parham
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Miss parvane naftchi
Street address
Ardabil University of Medical Sciences, Daneshgah st., Ardabil,
City
Ardabi
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil University of Medical Sciences
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

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Hossein Doustkami

Position

Cardiology, Interventional Fellowship, a member of the faculty of Ardabil University of medical scie

Other areas of specialty/work

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Web page address

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