

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

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

Protocol summary

2015-06-02, 1394/03/12

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

Registrant information

Name

Marzieh Peyravi Dehsorkhi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2006

Email address

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

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Email

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Web page address

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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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