

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of apple cider vinegar on glycemic index and lipid profile in patients with type 2 diabetes

Protocol summary

Registration timing: **prospective**

Study aim

Evaluation the effect of apple cider vinegar on glycemic index and lipid profile in patients with type 2 diabetes

Last update: **2018-11-05, 1397/08/14**

Update count: **0**

Design

Randomized clinical trial with parallel groups, not blinding, with control group

Registration date

2018-11-05, 1397/08/14

Settings and conduct

The target group is patients with type 2 diabetes that will be selected from patients visited in Golestan hospital in Ahvaz city and will be randomly divided into two intervention and control groups. Apple cider vinegar is the treatment and subjects will be followed for 8 weeks. Blood samples will be taken before and after the intervention period and the outcome variables will be measured between two groups.

Registrant information

Name

Sima Jafarirad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic patients with hyperlipidemia which only statin has been administrated for them, non-use of nutritional supplements, non-use of cider routinely or daily during 3 last months, non-insulin injection, body mass index between 18.5-34.9. Exclusion criteria: Renal and digestive diseases, pregnancy and lactation, insulin injection.

Recruitment status

Recruitment complete

Funding source

Intervention groups

Intervention group: apple cider vinegar with energy controlled diet based on the subject's need. Control group: energy controlled diet based on the subject's need

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Fasting blood glucose, triglyceride, total cholesterol, LDL-cholesterol, HDL-cholesterol, Hemoglobin A1c

Scientific title

Evaluation the effect of apple cider vinegar on glycemic index and lipid profile in patients with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140107016123N13**

Registration date: **2018-11-05, 1397/08/14**

Public title

Effect of apple cider vinegar on treatment of type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hyperlipidemic-diabetic patients with only statin administration
 Non-use of nutritional supplements
 Non-daily consumption of cider during last 3 months
 Non-insulin injection
 Body mass index between 18.5 to 34.9
 Age ranges between 30 to 60 years
 The willingness to participate in the study

Exclusion criteria:

Existing renal diseases
 Body mass index more than 35
 Pregnancy and lactation
 Insulin injection
 Patients with gastric disorders such as reflux and gastric ulcer
 Smoking more than one cigarettes a day
 Existing cancer

AgeFrom **30 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block.

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**

Ethics committee of Ahvaz Jundishapur University of
 Medical Sciences

Street address

Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-10-13, 1397/07/21

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Fasting blood sugar

Timepoint

Before and after intervention

Method of measurement

Enzymatic colorimetric

2**Description**

Total cholesterol

Timepoint

Before and after intervention

Method of measurement

Enzymatic colorimetric

3**Description**

Triglyceride

Timepoint

Before and after intervention

Method of measurement

Enzymatic colorimetric

4**Description**

High density lipoprotein-cholesterol

Timepoint

Before and after intervention

Method of measurement

Enzymatic colorimetric

5**Description**

low density lipoprotein-cholesterol

Timepoint

Before and after intervention

Method of measurement

Friedewald Equation

6

Description

Hemoglobin A1c

Timepoint

Before and after intervention

Method of measurement

Enzymatic colorimetric

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive apple cider vinegar with energy controlled diet based on the subject's need, for 8 weeks.

Category

Treatment - Other

2

Description

Control group will receive energy controlled diet based on the subject's need, for 8 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sima Jafarirad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammadreza Elahi

Position

Master of Sciences student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sima Jafarirad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available