

# 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)

##### Phone

+98 61 1373 8317

##### Email address

jafarirad-s@ajums.ac.ir

#### 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

**Age**From **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

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### 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

##### Street address

Golestan Highway

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

##### Phone

+98 61 3373 8317

##### Email

sjafarirad@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad Badavi

##### Street address

Golestan Highway

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

##### Phone

+98 61 3373 8383

##### Fax

##### Email

badavi-m@ajums.ac.ir

#### 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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Golestan Highway

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##### Email

Mr.elahi.2003@gmail.com

## 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**

### **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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**Phone**

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**Email**

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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