# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Investigating the short-term effects of apple vinegar consumption on systolic and diastolic blood pressure, pulse pressure and heart rate in healthy subjects

## Protocol summary

**Study aim**
Determination the short-term effects of apple vinegar consumption on the systolic and diastolic blood pressure, heart rate and pulse pressure in healthy subjects

**Design**
A clinical trial with a control group will be used and randomization will be done on the basis of random blocks.

**Settings and conduct**
Volunteers are selected based on the criteria for entering the study. On the day of the test, 4 hours after breakfast, the control group receives 200 cc of water while the test groups receive specific doses of 5% vinegar (22, 28 and 34 g vinegar), which are raised to 200 cc by adding water. Blood pressure is measured by a pressure indicator and heart rate on the basis of the electrocardiogram before receiving vinegar and with 15-minute intervals after receiving vinegar for 120 minutes using the same method. This study will be conducted at the cardiovascular Research Center of Guilan University of Medical Sciences.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria of study are: Healthy people with no history of allergy to vinegar, no smoking, having a body mass index between 18.5 to 29.9 Kg/m2. Exclusion criterion of study is: unwillingness of individuals to cooperate with the study procedure.

**Intervention groups**
The control group will receive single dose of 200 cc of mineral water. The intervention group 1 will receive single dose of 22 grams of 5% traditional apple vinegar whose volume is raised to 200 cc by adding water, the intervention group 2 will receive single dose of 28 grams of 5% traditional apple vinegar whose volume is raised to 200 cc by adding water, the intervention group 3 will receive single dose of 32 grams of 5% traditional apple vinegar whose volume is raised to 200 cc by adding water.

**Main outcome variables**
Reduction of systolic and diastolic blood pressure

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20171203037724N1**
Registration date: **2018-10-13, 1397/07/21**
Registration timing: **prospective**

Last update: **2018-10-13, 1397/07/21**
Update count: **0**

**Registration date**
2018-10-13, 1397/07/21

**Registrant information**

**Name**
Shirin Parvinroo

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 13 3348 6470

**Email address**
shirin.parvinroo@gums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-10-22, 1397/07/30

**Expected recruitment end date**
2019-01-20, 1397/10/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the short-term effects of apple vinegar consumption on systolic and diastolic blood pressure, pulse pressure and heart rate in healthy subjects

**Public title**
Investigating apple vinegar effects on blood pressure in healthy subjects
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
20 to 60 years healthy people No history of allergy to vinegar No digestive problems such as reflux and stomach problems No smoking a body mass index between 18.5 to 29.9 Kg/m2
**Exclusion criteria:**
Unwillingness of individuals to cooperate with the study procedure
**Age**
From **20 years** old to **60 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method and description: Randomization method is based on gradual referrals and having inclusion criteria and interest in participating in the study. Randomization unit: individual Randomization layers: gender Randomization Tool: Random Allocation Software The method of creating a random sequence: Sequence Allocation concealment: Selection sequence of samples is divided into four groups of women (20) and men (20) that are kept in sealed letters at the Cardiovascular Diseases Research Center of Heshmat Hospital at Rasht and are opened at the beginning of the study each morning and closed at night from outset of the study. Based on the sex of the samples and having the criteria for entering the sequencing, the samples are placed in one of the four groups (low dose - moderate dose- high dose and control).
**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 Guilan University of Medical Sciences
**Street address**
Deputy of Research and Technology of Guilan University of Medical Sciences, opposite 17th Shahrivar Hospital, Shahid Siadati St., Namjoo Blv.
**City**
Rasht
**Province**
Guilan
**Postal code**
41446-66949
**Approval date**
2018-06-11, 1397/03/21
**Ethics committee reference number**
IR.GUMS.REC.1397.102

## Health conditions studied

### 1

**Description of health condition studied**
Blood pressure
**ICD-10 code**
I10
**ICD-10 code description**
Essential (primary) hypertension

## Primary outcomes

### 1

**Description**
Reduction of systolic and diastolic blood pressure
**Timepoint**
Ṣystolic and diastolic blood pressure will be measured before intervention and with 15-minute intervals after intervention up to 120 minutes.
**Method of measurement**
Systolic and diastolic blood pressure will be measured by a digital sphygmomanometer.

## Secondary outcomes

### 1

**Description**
Pulse pressure
**Timepoint**
Before intervention and with 15-minute intervals after intervention up to 120 minutes
**Method of measurement**

Difference of systolic and diastolic blood pressure

**2**

**Description**
Heart rate
**Timepoint**
Before intervention and end of intervention
**Method of measurement**
Electrocardiogram

## Intervention groups

**1**

**Description**
The intervention group 1 will receive single dose of 22 grams of 5% traditional apple vinegar whose volume is raised to 200 cc by adding water.
**Category**
Prevention

**2**

**Description**
The intervention group 2 will receive single dose of 28 grams of 5% traditional apple vinegar whose volume is raised to 200 cc by adding water.
**Category**
Prevention

**3**

**Description**
The intervention group 3 will receive single dose of 32 grams of 5% traditional apple vinegar whose volume is raised to 200 cc by adding water.
**Category**
Prevention

**4**

**Description**
The control group will receive single dose of 200 cc of mineral water.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Cardiovascular Diseases Research Center, Dr. Heshmat Hospital
**Full name of responsible person**
Shirin Parvinroo
**Street address**
Bayani Street., Mosalla Square.
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Rasht University of Medical Sciences
**Full name of responsible person**
Shadman Nemati
**Street address**
Deputy of Research and Technology of Guilan University of Medical Sciences, opposite 17th Shahrivar Hospital, Shahid Siadati St., Namjoo Blv.
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4144666949
**Phone**
+98 13 3333 5820
**Email**
nemati@gums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Rasht 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**
Rasht University of Medical Sciences
**Full name of responsible person**
Shirin Parvinroo
**Position**
Assistant Professor

**Latest degree**
Ph.D.
**Other areas of specialty/work**
Traditional pharmacy
**Street address**
School of Pharmacy, Guilan University of Medical Sciences Campus, Fouman – Saravan Road
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## Person responsible for scientific inquiries

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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**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available