

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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

Systolic 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.

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3361 8177

Fax

+98 13 3361 8177

Email

shirin.parvinroo@gums.ac.ir

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.

City

Rasht

Province

Guilan

Postal code

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

City

Rasht

Province

Guilan

Postal code

4194173774

Phone

+98 13 3348 6470

Email

shirin.parvinroo@gums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Shirin Parvinroo

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Phone

+98 13 3348 6470

Email

shirin.parvinroo@gums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Shirin Parvinroo

Position

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4194173774

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+98 13 3348 6470

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

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