Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical Trial of the Effect of Processed Berberis vulgaris in Apple Vinegar and Apple Vinegar on Lipid Profile, Insulin Resistance, Weight, Hypertension and Inflammatory Indices in Type II Diabetic Patients

Protocol summary

Summary

1) Major eligibility object: Effect of Processed Berberis vulgaris on Metabolic Syndrome in Type2 Diabetic Patients. 2) Design: In this clinical randomized trial, 57 patients with metabolic syndrome based on WHO criteria were recruited. 3) Setting and conduct: Patients randomly assigned into 3 groups: 1) processed Berberis vulgaris (n =19), 2) apple vinegar group (n =19) and 3) control group. 4) Participants including criteria: Inclusion criteria: obesity (BMI>30kg/m2) or WHR>0.9(men) and 0.8(women); hypertriglyceridemia (TG>150 mg/dl); HDL<35(men) and <39(women); hypertension >90/140mmHg. Exclusion criteria: renal, hepatic, gastrointestinal and thyroid disease; diet therapy; insulin therapy 5) Intervention: Berberis vulgaris fed 1table spoon Berberis vulgaris that incubated in apple vinegar for 40 days, 2) apple vinegar group that fed 2table spoon apple vinegar daily and 3) control group with no intervention. 6) Main outcome measures: Weight, BMI, body fat, fat free mass, total-, HDL-, LDL-cholesterol, triglyceride, glucose, insulin, HOMA-IR, malondialdehyde, high sensitive CRP and interleukin-6 concentrations, as well as systolic- and diastolic blood pressure were measured at the baseline and end of weeks 2, 4 and 8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107096984N1**
Registration date: **2011-07-16, 1390/04/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-16, 1390/04/25

Registrant information

Name
Mahdieh Golzarand

Name of organization / entity
Obesity Research Center

Country
Iran (Islamic Republic of)

Phone
+98 21 2243 2500

Email address
mahdieh_golzarand@yahoo.com

Recruitment status

Recruitment complete

Funding source

Nutritional Research Center of Tabriz University of Medical Sciences, Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2006-06-22, 1385/04/01

Expected recruitment end date

2006-08-23, 1385/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of the Effect of Processed Berberis vulgaris in Apple Vinegar and Apple Vinegar on Lipid Profile, Insulin Resistance, Weight, Hypertension and Inflammatory Indices in Type II Diabetic Patients

Public title

Effect of Berebris vulgaris on Metabolic Syndrome Components

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: obesity (BMI>30kg/m2) or WHR>0.9(men) and 0.8(women); hypertriglyceridemia (TG>150 mg/dl); HDL<35(men) and <39(women); hypertension >90/140mmHg. Exclusion criteria: renal, hepatic, gastrointestinal and thyroid disease; diet therapy; insulin therapy

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Golgasht st, Azadi blvd

City

Tabriz

Postal code

Approval date

2006-09-23, 1385/07/01

Ethics committee reference number

8545

Health conditions studied

1

Description of health condition studied

Type 2 Diabete

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes Mellitus

Primary outcomes

1

Description

Glucose

Timepoint

Baseline and 2, 4 and 8 weeka after intervention

Method of measurement

Biochemistery analysis

2

Description

Blood pressure

Timepoint

Baseline and 2, 4 and 8 weeka after intervention

Method of measurement

Manometer

3

Description

Malondialdehyde

Timepoint

Baseline and 2, 4 and 8 weeka after intervention

Method of measurement

Biochemistery analysis

4

Description

Inflammatoru indices

Timepoint

Baseline and 2, 4 and 8 weeka after intervention

Method of measurement

Biochemistery analysis

5

Description

Insulin

Timepoint

Baseline and 2, 4 and 8 weeka after intervention

Method of measurement

Biochemistery analysis

6

Description

Anthropometric Indices

Timepoint

Baseline and 2, 4 and 8 weeka after intervention

Method of measurement

Bioelectric impedance

7

Description

Lipid profile

Timepoint

Baseline and 2, 4 and 8 weeka after intervention

Method of measurement

Biochemistery analysis

Secondary outcomes

empty

Intervention groups

1

Description

Processed Berberis vulgaris in domestic apple vinegar- one table spoon with lunch for 8 weeks

Category

Prevention

2

Description

Domestic Apple Vinegar- 2 table spoon with lunch for 8 weeks

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrin Clinic of Sina Hospital

Full name of responsible person

Akbar Aliasgarzadeh

Street address

Azadi st

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutritional Research Center

Full name of responsible person

Mousa Ghaiour

Street address

Nutritional Research Center, Faculty of Health and Nutrition, Atar-e-Neishabouri st- Golgasht st

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nutritional Research Center

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Mrs.Zamiran

Street address

Golgasht st, Azadi st

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

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

Person responsible for general inquiries

Contact

Name of organization / entity

Obesity Research Center, Research Institue for Endocrine Science, Shaheed Beheshti University of Med

Full name of responsible person

Mahdieh Golzarand

Position

MSc in Nutrition

Other areas of specialty/work

Street address

No.24, Shahid Arabi St, Yemen Blvd, Chamran Exp

City

Tehran

Postal code

19395-4763

Phone

+98 21 2243 2500

Fax

+98 21 2240 2463

Email

mahdieh_golzarand@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nutritional Research Centar, Tabriz University of Medical Sciences

Full name of responsible person

Mehrangiz Ebrahimi Mamaghani

Position

PhD in Nutrition

Other areas of specialty/work

Street address

Atar-e-Neishabouri st, Golgasht st

City

Tabriz

Postal code

Phone

+98 41 1335 7581

Fax

Email

mehrangize@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Science, Shahid Beheshti University of Med

Full name of responsible person

Mahdieh Golzarand

Position

MSc in Nutrition

Other areas of specialty/work

Street address

No.24, Shahid Arabi St, Yemen Blvd, Chamran Hwy

City

Tehran

Postal code

19395-4763

Phone

+98 21 2243 2500

Fax

+98 21 2240 2463

Email

mahdieh_golzarand@yahoo.com

Web page address

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