

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effect of dark chocolate consumption on ApoB, ApoA-1, lipid profile, hsCRP, glycemic control and blood pressure in type 2 Diabetic patients with hypertension.

Protocol summary

Summary

In this parallel randomized controlled trial, 70 hypertensive men and women with type 2 diabetes will be recruited from Institute of Endocrinology & Metabolism of Iran University of Medical Sciences. The subjects will be 35-65 years old with established and stably-treated type 2 diabetes mellitus for at least 1 year. Inclusion criteria are BMI \leq 40 kg/m², HbA1C < 9%, Blood pressure \geq 130/80 mmHg and no regular use of any drugs or supplements with antioxidative (β -carotene, vitamins C or E) or lipid-lowering properties. All volunteers will either life-long nonsmokers or reported smoking abstinence of at least 5 years before study and they also will not use alcohol and drugs. Exclusion criteria are being allergic to chocolate, congestive heart failure, malignancies, chronic kidney, hepatic and thyroid diseases, severe cardiac arrhythmias, inflammation, using insulin, following vegetarian or weight-reducing diets. Participants enrolled for the study would be allowed to continue their normal, daily lifestyle and eating habits. Prior to the study, the subjects will be required to complete 3-days 24-hour dietary recall and Diets will be analyzed for calorie, macronutrients and antioxidant content. Participants will consume 25 g daily of either white chocolate (without flavanol) or dark chocolate (with flavanol) for 8 weeks. Blood samples will be obtained after an overnight fasting before and after the study. All anthropometric and physical activity variables and blood pressure will be measured both before and after the trial and also Serum lipids, ApoB, ApoA-1, hsCRP, fasting blood glucose, HbA1c and blood were measured at baseline and after 8 wks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812222602N3**

Registration date: **2010-03-13, 1388/12/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-03-13, 1388/12/22

Registrant information

Name

Shahryar Eghtesadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Iran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-03-10, 1389/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dark chocolate consumption on ApoB, ApoA-1, lipid profile, hsCRP, glycemic control and blood pressure in type 2 Diabetec patients with hypertention.

Public title

Effect of Dark chocolate consumption in hypertensive type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Being volunteer or wishing to attend, 35-65 y old, diagnosed with type 2 diabetes for at least 1 year (FPG \geq 126 mg/dl or 2hPG \geq 200 mg/dl), BMI \leq 40 kg/m², HbA1C < 9%, Blood pressure \geq 130/80 mmHg and no regular use of any drugs or supplements with antioxidative (β -carotene, vitamins C or E) or lipid-lowering properties. Exclusion criteria: Allergy to chocolate, Taking insulin, Smoking cigarette, drinking alcohol or drug abuse, congestive heart failure, malignancies, chronic kidney , hepatic and thyroid diseases , severe cardiac arrhythmias, inflammation following vegetarian or weight-reducing diet 2 months before the study ,Changing medication dosage or physical activity level 2 mo before or during the study.

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Health, Iran University of Medical Sciences

Street address

Alvand Ave, Arjanteen Square

City

Tehran

Postal code

Approval date

2010-07-18, 1389/04/27

Ethics committee reference number

1421

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Decrease Low Density Lipoprotein

Timepoint

8 weeks

Method of measurement

Laboratory kit

2

Description

decrease blood pressure

Timepoint

8 week

Method of measurement

sphygmomanometer

3

Description

decrease Apo B

Timepoint

8 weeks

Method of measurement

immunoturbidimetry

4

Description

increase ApoA-1

Timepoint

8 weeks

Method of measurement

immunoturbidimetry

5

Description

Decrease Triglyceride (TG)

Timepoint

8 weeks

Method of measurement

Laboratory Kit

6

Description

Decrease Fasting Blood Sugar (FBS)

Timepoint

8 weeks

Method of measurement

Enzymatic

7

Description

Decrease high sensitivity C-reactive protein (hs-CRP)

Timepoint

8 weeks

Method of measurement

Immunoturbidimetry

8

Description

decrease HbA1C

Timepoint

8 weeks

Method of measurement

Laboratory Kit

Secondary outcomes

empty

Intervention groups

1

Description

control: 25 gr of white chocolate for 8 weeks

Category

Other

2

Description

intervention: 25 gr of dark chocolate for 8 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Institute of Endocrinology & Metabolism of Iran
University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mohsen Asadi Lari

Street address

Hemmat high Way

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

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

School of Health, Iran University of Medical Sciences

Full name of responsible person

Dr. Shahriar Eghtesadi

Position

Full Professor

Other areas of specialty/work

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Dr Shahriar Eghtesadi

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****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