

# 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/m<sup>2</sup>, HbA1C < 9%, Blood pressure  $\geq$  130/80 mmHg and no regular use of any drugs or supplements with antioxidative ( $\beta$ -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)

###### Phone

+98 21 8877 9118

###### Email address

egtesadi@iums.ac.ir

##### 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/m<sup>2</sup>, HbA1C < 9%, Blood pressure  $\geq$  130/80 mmHg and no regular use of any drugs or supplements with antioxidative ( $\beta$ -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

##### Street address

School of Health, Alvand Ave, Arjanteen Square

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##### Email

egtesadi@yahoo.com

##### Web page address

## Person responsible for scientific 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****Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

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*