

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jul 2026

**The effect of dark chocolate intake on serum nitric oxide, angiotensin $\square$ , adiponectin, inflammatory cytokines (IL-6, TNF $\alpha$ ) and blood pressure in patients with type 2 diabetes.**

### Protocol summary

#### Summary

Polyphenol compounds are found in some foods like cocoa and have beneficial effects on inflammatory factors. According to that appropriate diet are very important in diabetics patients, so it is important to consume some foods that could be effective on treatment and reduction of diabetes complications. This study was designed to investigate the effect of dark chocolate (that contains many polyphenols) on serum nitric oxide, angiotensin $\square$ , adiponectin, inflammatory cytokines and blood pressure in diabetic patients. The study people are patients with type 2 diabetes. Inclusion criteria are 30-60 years old type 2 diabetic patients with no other diseases and the key exclusion criteria is BMI more than 35. sample size is 50 that will be divided into two groups (dark chocolate group and the control). The period of intervention is 2 months. The primary outcomes are nitric oxide angiotensin $\square$ , adiponectin, inflammatory cytokines (IL-6, TNF $\alpha$ ) and blood pressure.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2015022116123N5**

Registration date: **2015-03-11, 1393/12/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2015-03-11, 1393/12/20

#### Registrant information

##### Name

Sima Jafarirad

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1373 8317

##### Email address

jafarirad-s@ajums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

#### Expected recruitment start date

2015-03-01, 1393/12/10

#### Expected recruitment end date

2015-06-20, 1394/03/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of dark chocolate intake on serum nitric oxide, angiotensin $\square$ , adiponectin, inflammatory cytokines (IL-6, TNF $\alpha$ ) and blood pressure in patients with type 2 diabetes.

#### Public title

dark chocolate effect on cardiovascular side effect of diabetes

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: no food supplement consumption; body mass index 18.5-34.9; 30-60 years old; using only blood glucose reducing drugs, Metformin and Glibenclamide;

willing to participate. Exclusion criteria: no appropriate corporation; any other disease; Obesity[] (body mass index more than 34.9); pregnancy and lactating.

#### Age

From **30 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur  
University of Medical Sciences

##### Street address

The Ethics Committee, Vice Chancellor for Research  
and Technology, Ahvaz Jundishapur University of  
Medical Sciences, University City, Golestan Blvd.

##### City

Ahvaz

##### Postal code

#### Approval date

2015-01-31, 1393/11/11

#### Ethics committee reference number

ajums.REC.1393.407

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Mellitus type 2

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

nitric oxide

#### Timepoint

at the first and at the end of intervention period

#### Method of measurement

ELISA

### 2

#### Description

adiponectin

#### Timepoint

at the first and at the end of intervention period

#### Method of measurement

ELISA

### 3

#### Description

angiotensin[]

#### Timepoint

at the first and at the end of intervention period

#### Method of measurement

ELISA

### 4

#### Description

Interleukine- 6

#### Timepoint

at the first and at the end of intervention period

#### Method of measurement

ELISA

### 5

#### Description

Tumor necrosis Factor- $\alpha$

#### Timepoint

at the first and at the end of intervention period

#### Method of measurement

ELISA

### 6

#### Description

blood pressure

#### Timepoint

at the first and at the end of intervention period

#### Method of measurement

Mercury sphygmomanometer

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention: diet controlling; 30 gram of 84% dark chocolate per day, for two months

### Category

Treatment - Other

## 2

### Description

control: diet controlling, for two months

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Golestan hospital, Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Dr. Jafarirad

#### Street address

Golestan Hospital, Farvardin Street, Golestan

#### City

Ahvaz

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Vice Chancellor for Research and Technology

#### Street address

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Blvd.

#### City

Ahvaz

### 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 and Technology, Ahvaz Jundishapur 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

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Nutrition and Metabolic Disease Research Center, Ahvaz Jundishapur University of Medical Sciences, A

#### Full name of responsible person

Dr. Sima Jafarirad

#### Position

PhD

#### Other areas of specialty/work

#### Street address

Nutrition and Metabolic Disease Research Center, Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Blvd.

#### City

Ahvaz

#### Postal code

#### Phone

+98 61 3373 8317

#### Fax

#### Email

jafarirad-s@ajums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences, paramedics schools

#### Full name of responsible person

nina ayoobi

#### Position

master student of nutrition

#### Other areas of specialty/work

#### Street address

Ahvaz Jundishapur University of Medical Sciences, University City, Golestan Blvd, paramedics schools

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#### Postal code

#### Phone

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#### Fax

#### Email

n.ayoobi@gmail.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*