

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 α) 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 α) 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 α) 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- α

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

City

Ahvaz

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