

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of dark chocolate intake on serum lipid profiles, fasting blood sugar and C-reactive protein in patients with type 2 diabetes

Protocol summary

Summary

Polyphenol compounds are found in some foods like cocoa and have beneficial effects on lipid profiles, insulin production and insulin sensitivity. 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 lipid profile and blood sugar 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 30. sample size is 30 that will be divided into two groups (dark chocolate group and the control). The period of intervention is 2 months. The primary outcomes are fasting blood sugar and lipid profiles (LDL-C, HDL-C, TG and total cholesterol).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010716123N1**

Registration date: **2014-06-09, 1393/03/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-06-09, 1393/03/19

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

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

Expected recruitment start date

2014-10-21, 1393/07/29

Expected recruitment end date

2015-03-30, 1394/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dark chocolate intake on serum lipid profiles, fasting blood sugar and C-reactive protein in patients with type 2 diabetes

Public title

dark chocolate effect on diabetes treatment process

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: no food supplement consumption; body mass index 18.5-29.9; 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 30); 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: **30****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**

2013-10-26, 1392/08/04

Ethics committee reference number

ajums.REC.1392.157

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**

fasting blood glucose

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

2**Description**

HgA1C

Timepoint

at the first and at the end of intervention period

Method of measurement

Enzymatic method

3**Description**

LDL

Timepoint

at the first and at the end of intervention period

Method of measurement

Friedewald formula

4**Description**

TG

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

5**Description**

HDL

Timepoint

at the first and at the end of intervention period

Method of measurement

Autoanalyzer

6**Description**

hs-CRP

Timepoint

at the first and at the end of intervention period

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**Intervention: diet controlling; 40 gram of 85% dark
chocolate per day, for two months**Category**

Treatment - Other

2

Description

control: diet controlling, for two months

Category

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 1373 8317

Fax

Email

jafarirad-s@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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

Full name of responsible person

Dr. 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 1373 8317

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