

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of chocolate consumption on oxidative stress conditions, glucose and lipid profile and insulin resistance in patients with metabolic syndrome

Protocol summary

Summary

This study is a blind clinical trial. the aim of this study is to determine the effects of dark chocolate consumption on antioxidant status, serum glucose, lipid profile and insulin resistance in patients with metabolic syndrome. 114 patients 30-60 years of age with diagnosed metabolic syndrome that had been detected by khatamolanbia Center, After filling out the consent, will be recruited to the study. Period of intervention is 8 weeks. According to random assignment, patients will be divided into three groups: 1) 20g/d dark chocolate consumption , or 2) 40 gr/day dark chocolate consumption, or 3) control group that receives no intervention. Anthropometric and biochemical measurements, medical and general information and 24-hour dietary recalls will be collected at the beginning and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022812122N2**

Registration date: **2013-04-28, 1392/02/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-28, 1392/02/08

Registrant information

Name

Faezeh Poursoleiman

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1623 4120

Email address

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences.

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of chocolate consumption on oxidative stress conditions, glucose and lipid profile and insulin resistance in patients with metabolic syndrome

Public title

effect of dark chocolate consumption on metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

diagnosed metabolic syndrome based on NCEP definition by speceialist and age of 30 to 60 years; without any kidney, liver, heart, stomach,thyroid disease, anemia and Fibrocystic breast; not taking vitamin and antioxidant supplements in recent months; not pregnant or lactating. exclusion criteria: taking less than 80% of given chocolates; changing the type and dose of routine

medicine.
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: **114**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Department of Research and technology, Shahid
Sadoughi University
Street address
University Department, Bahonar square و غشطی
City
Yazd
Postal code
Approval date
2013-02-24, 1391/12/06
Ethics committee reference number
172757/1/17/ب

Health conditions studied

1

Description of health condition studied
metabolic syndrome
ICD-10 code
Z86.3
ICD-10 code description
Personal history of endocrine, nutritional and metabolic
diseases

Primary outcomes

1

Description
oxidative stress condition
Timepoint
Before and after intervention
Method of measurement
measurement of plasma free radical trapping capacity
,and serum MDA

2

Description
Fasting Blood Sugar
Timepoint
Before and after intervention
Method of measurement
enzymatic

3

Description
insulin resistance
Timepoint
Before and after intervention
Method of measurement
HOMA calculation

4

Description
serum triglyceride
Timepoint
Before and after intervention
Method of measurement
enzymatic

5

Description
total cholesterol
Timepoint
Before and after intervention
Method of measurement
enzymatic

6

Description
High density Lipoprotein (HDL)
Timepoint
Before and after intervention
Method of measurement
enzymatic

7

Description
low density Lipoprotein (IDL)
Timepoint
Before and after intervention
Method of measurement
freidewald formula

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1= two times Dark chocklate consumption per day, each time 10gr

Category

Treatment - Other

2

Description

control group= recieve no intervension

Category

Treatment - Other

3

Description

intervention group2= 2 times dark chocklate per day, each time 20gr

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Street address

Diabetes Center, Afshar hospital, Jomhuri Blvd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Street address

Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Yazd Shahid Sadoughi 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

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Akram Naghdipour

Position

Student of MSc Health Sciences in Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD in Nutritional Sciences

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Postal code**Phone**

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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