Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Tocomas added to canola oil on oxidative-nitrosative stress parameters, insulin sensitivity and microalbuminuria in type 2 diabetic patients

Protocol summary

Summary

The aim of this study is to investigate the Effect of Tocomas (tocotrienol rich fraction) added to canola oil on oxidative-nitrosative stress parameters, insulin sensitivity and microalbuminuria in type 2 diabetic patients. In this Double blinded randomized controlled trial, 50 men and women with type 2 diabetes aged 35-70 years old, who are eligible for this study, will be recruited from Institute of Endocrinology & Metabolism of Iran University of Medical Sciences. Informed consent form will be completed by each participant at the beginning of the study, participants will be randomly assigned to daily receive either 15 grams of canola oil reached in tocomas suspension in the form of 525 mg tocomas (200 mg tocotrienols) in each 15 grams of canola oil or 15 grams pure canola oil for 8 weeks. Then, we will substitute this oil for daily oil consumption in both groups. Prior to the study, the subjects will be required to complete 3-days 24-hour dietary recall. Diets will be analyzed for calorie and macro_ micronutrients content. Blood samples will be obtained after an overnight fast before and after the study. All anthropometric and physical activity variables will be measured both before and after the trial. Diets and medications dosage will be held constant throughout the study and each subject's exercise level will be kept constant and monitored by physical activity questionnaires (IPAQ).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008092365N2**
Registration date: **2010-08-28, 1389/06/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-08-28, 1389/06/06

Registrant information

Name
Mohammad Reza Vafa
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4734
Email address
vafa.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-03-06, 1389/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Tocomas added to canola oil on oxidative-nitrosative stress parameters, insulin sensitivity and microalbuminuria in type 2 diabetic patients

Public title

Effects of Tocomas added to canola oil on oxidative-nitrosative stress parameters, insulin sensitivity and

microalbuminuria in type 2 diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Being volunteer or Wishing to attend, 35-60 y old, diagnosed with type 2 diabetes for at least 1 year (FPG ≥ 126 mg/dl or 2hPG ≥ 200 mg/dl), BMI ≤ 40 kg/m2, no cancer or thyroid or liver disease Exclusion criteria: Taking insulin, Changing medication dosage or physical activity level 2 mo before or during the study, Pregnancy, lactation, dialysis, Using multivitamins, minerals, or other antioxidants during 1 month prior to the study, Using warfarins or other anticoagulant drugs

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Public Health, Iran University Of Medical Sciences

Street address

Arjantin Square, Alvand Avenue

City

Tehran

Postal code

1516846514

Approval date

2010-07-18, 1389/04/27

Ethics committee reference number

1421

Health conditions studied

1

Description of health condition studied

Non-insulin-dependent diabetes mellitus

ICD-10 code

E-12

ICD-10 code description

Malnutrition-related diabetes mellitus

Primary outcomes

1

Description

Increase Total Antioxidant Capacity (TAC)

Timepoint

8 weeks

Method of measurement

Spectrophotometery

2

Description

decrease nitric oxide (NO)

Timepoint

8 weeks

Method of measurement

colorimeter

Secondary outcomes

1

Description

Fasting Insulin

Timepoint

8 weeks

Method of measurement

RIA

2

Description

HOMA Index

Timepoint

8 weeks

Method of measurement

Calculation

3

Description

high sensitivity C-reactive protein (hs-CRP)

Timepoint

8 weeks

Method of measurement

Immunoturbidimetry

Intervention groups

1

Description
Tocomas added to canola oil (525 mg Tocomas per 15 gram canola oil), substitution with daily oil consumption, for 8 weeks
Category
Prevention

2

Description
canola oil (15 gram) substitution with daily oil consumption, for 8 weeks
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Institute of Endocrinology & Metabolism of Iran University of Medical Sciences
Full name of responsible person
Dr Iraj Heydari
Street address
Institute of Endocrinology & Metabolism of Iran Universityof Medical Sciences, Firozgar Hospital, Vali-Aser Square
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
Iran University of Medical Sciences, Hemat Express 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Mohammad Reza Vafa
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Alvand Ave, Arjantin Square
City
Tehran
Postal code
Phone
+98 21 8877 9118
Fax
Email
rezavafa@iums.ac.irrezavafa@yahoo.com
Web page address

Person responsible for updating data

Contact

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