Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of supplementation with red grape seed extract on antioxidant status, lipid peroxidation and serum lipid profile in patient with type II diabetes

Protocol summary

Summary

The aim of this study is to determine the effect of grape seed extract supplementation on biochemical and Redox indices in patients with type 2 diabetes. Fifty seven patients with type 2 diabetes who met the inclusion criteria were included in the study. These patients were recruited from Imam Reza endocrine clinic of Tabriz University of Medical Sciences, Iran. The patients were randomly assigned (22=placebo and 27=grape seed extract), in a double blind fashion, to receive placebo or grape seed extract (200mg/day) for 8 weeks. Weight, height, and blood pressure were measured at the first and the end of study. Fasting venous blood samples were taken before and after the treatment for biochemistry and Redox indices, including: fasting blood sugar, lipid profiles, HbA1C, Serum malondialdehyde (MDA), Total antioxidant capacity (TAC), superoxide dismutase (SOD), glutation peroxidase (GPX), 3-day food intake 24h recalls were taken measured for all participant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009133253N3**
Registration date: **2010-09-14, 1389/06/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-14, 1389/06/23

Registrant information

Name

Parvin Dehghan

Name of organization / entity

Tabriz MedicalSience University

Country

Iran (Islamic Republic of)

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Email address

bahrampg@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tabriz Drug Appling Research Center

Expected recruitment start date

2009-11-16, 1388/08/25

Expected recruitment end date

2010-03-17, 1388/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supplementation with red grape seed extract on antioxidant status, lipid peroxidation and serum lipid profile in patient with type II diabetes

Public title

Effect of supplementation with red grape seed extract in patient with type II diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having diabetes for at least five years, 30 to 65 years of age, voluntary consent for participation in the study, using drugs to control blood glucose and not using insulin Exclusion criteria: using antioxidant supplements in the previous three months, persons with

gastric treatment, pregnant and lactating women, presence of hepatic or renal failure, hyper and hypothyroidism, celiac, diarrehea, recent surgery or acute infection, using anticoagulant drugs

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **57**

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
Tabriz University of Medical Sciences

Street address
Golbad street, Tabriz

City
Tabriz

Postal code

Approval date
2009-10-28, 1388/08/06

Ethics committee reference number
5/4/5910

Health conditions studied

1

Description of health condition studied
type 2 diabetes

ICD-10 code
E11

ICD-10 code description
non-Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
antioxidant indices

Timepoint
8 weeks after intervention after

Method of measurement
Assessments of changes in TAC.SOD, GPX.MDA

2

Description
lipid profiles

Timepoint
8 weeks after intervention after

Method of measurement
laboratory

3

Description
FBS and HbA1C

Timepoint
8 weeks after intervention

Method of measurement
laboratory

Secondary outcomes

1

Description
Blood pressure

Timepoint
8 weeks after the supplementation

Method of measurement
Sphygmometer

2

Description
Body Mass Index

Timepoint
8 weeks after the supplementation

Method of measurement
Weight(Kg)/height(m2)

Intervention groups

1

Description
200mg/day of red grape seed extract for 8 weeks

Category
Treatment - Drugs

2

Description
Placebo with the same dose for 8 weeks

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza endocrine clinic
Full name of responsible person
Street address
Golbad street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Drug Applied Reaearch Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr Babae Hossein
Street address
Drug Applied Reaearch Center, Tabriz University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Drug Applied Reaearch Center, Tabriz 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
Health and Nutrition Faculty, Tabriz University of Medical Sciences
Full name of responsible person
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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