

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 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 MedicalScience University

Country

Iran (Islamic Republic of)

Phone

+98 937 139 5660

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, diarrhea, 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

Bahram Pourghassem

Position

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Other areas of specialty/work

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Health and Nutrition Faculty

Full name of responsible person

Abedini Somayeh

Position

MS

Other areas of specialty/work

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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