Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the effect of portalaca olearaca on oxidative stress status in patients with type 2 diabetes: A cross-over study

Protocol summary

Summary

Objective: Assessment of the effect of purslane seed on oxidative stress status in patients with type 2 diabetes. Design: Randomized cross over trial. Participants: Forty two diabetic patients who referred to Endocrinology and Metabolism Institute of Isfahan. Aged 35-65 years old; Non-smokers and lack of alcohol use; Not consuming supplements two weeks before the study and during the study; Non-pregnant and non-lactating women. No Change in dosage and type of medications at least two months prior to study; No history of chronic diseases. Exclusion criteria: Changes in diet or physical activity patterns for any reason; injection of Insulin during the study; Changes in dosage and type of medications throughout the study; Unwillingness to continue. Setting and conduct: Participants will be randomly assigned into two groups. Intervention group: will receive 10 gram powdered purslane seed with 240 cc low fat yogurt and control group: will use only 240 cc low fat yogurt for 5 weeks. Participants will move to the alternate arm after 2 weeks wash out period. The participants will be asked not to change their regular diet, medicine and activity during the study. To assess the compliance of the participants we will assess dietary intake of subjects by the use of dietary record once in every two weeks and Physical activity level will also be assessed by a physical activity record during the study. Main outcomes: biochemical measures including total antioxidant capacity (TAC), Serum malondialdehyde (MDA) and Serum oxidized LDL level. Outcomes will be measured at baseline and after each phase of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203241485N9**
Registration date: **2012-08-03, 1391/05/13**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-08-03, 1391/05/13

Registrant information

Name

Ahmad Esmaillzadeh

Name of organization / entity

Department of Nutrition, School of Public Health, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-04-13, 1391/01/25

Expected recruitment end date

2012-06-14, 1391/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of portalaca olearaca on oxidative stress status in patients with type 2 diabetes: A cross-over study

Public title

Effect of portalaca olearaca on oxidative stress status in

patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non- Insulin dependent type 2 diabetic Patients; Non-smokers and lack of alcohol use; Not consuming supplements two weeks before the study and during the study; Non-pregnant and non-lactating women; Aged 35-65 years; No Change in dosage and type of medications at least two months prior to study; No history of hepatic, renal, lung, cardiovascular, kidney stone, thyroid diseases and gastro-intestinal bleeding; No history of myocardial infarction and stroke; Not affected by Severe non-proliferative or proliferative retinopathy; Not affected by malignant hypertension. Exclusion criteria: Change in diet or physical activity patterns during the study; injection of Insulin during study; Changes in dosage and type of medications throughout the study; Unwillingness to continue.

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Ave, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2012-03-10, 1390/12/20

Ethics committee reference number

190151

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Serum Malondialdehyde level

Timepoint

At baseline and after each phase of intervention

Method of measurement

Commercial kits

2

Description

Serum oxidized LDL level

Timepoint

At baseline and after each phase of intervention

Method of measurement

Commercial kits

3

Description

Total antioxidant capacity level

Timepoint

At baseline and after each phase of intervention

Method of measurement

Commercial kits

Secondary outcomes

1

Description

fasting Plasma glucose level

Timepoint

At baseline and after each phase of intervention

Method of measurement

Enzymatic method

2

Description

Weight

Timepoint

At baseline and after each phase of intervention

Method of measurement

Scale

3

Description
Waist circumference
Timepoint
At baseline and after each phase of intervention
Method of measurement
Un stretched measure

4

Description
Systolic blood pressure
Timepoint
At baseline and after each phase of intervention
Method of measurement
Mercurial sphygmomanometer

5

Description
Diastolic blood pressure
Timepoint
At baseline and after each phase of intervention
Method of measurement
Mercurial sphygmomanometer

6

Description
Serum Insulin level
Timepoint
At baseline and after each phase of intervention
Method of measurement
IRMA

7

Description
HOMA-IR
Timepoint
At baseline and after each phase of intervention
Method of measurement
Formula

8

Description
Serum triglyceride level
Timepoint
At baseline and after each phase of intervention
Method of measurement
Enzymatic method

9

Description
Serum total cholesterol level
Timepoint
At baseline and after each phase of intervention
Method of measurement
Enzymatic method

10

Description
Serum LDL level
Timepoint
At baseline and after each phase of intervention
Method of measurement
Friedewald formula

11

Description
Serum HDL level
Timepoint
At baseline and after each phase of intervention
Method of measurement
Enzymatic method

12

Description
Serum Apo A level
Timepoint
At baseline and after each phase of intervention
Method of measurement
Immunoturbidimetry

13

Description
Serum Apo B level
Timepoint
At baseline and after each phase of intervention
Method of measurement
Immunoturbidimetry

Intervention groups

1

Description
Intervention group: Will receive 10 g/day of Purslane seed powder with 240cc low fat yogurt for 5 weeks
Category
Treatment - Other

2

Description
Control group: Will receive 240cc/day low fat yogurt for 5 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and Metabolism Institute of Isfahan
Full name of responsible person
Dr Ahmad Esmaeilzadeh

Street address
Endocrinology and Metabolism Institute of Isfahan, Khoram Street, Jomhoori Square, Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Adibi
Street address
Hezar Jerib Ave, Isfahan University of Medical Sciences
City
Isfahan
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, Isfahan 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
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Person responsible for updating data

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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