

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of portalaca olearaca on glycemic status and lipid profiles in patients with type 2 diabetes: A cross-over study

Protocol summary

Summary

The objective: evaluation of the effect of purslane seed on glycemic status and lipid profiles in patients with type 2 diabetes. Design: randomized cross over trial.

Participants: 42 diabetic patients who referred to Endocrinology and Metabolism Institute of Isfahan; age 35-65 years; Not smoking and alcohol; Not consume supplement two weeks before the study and during the study; Not pregnant and lactation; No Change in dosage and type of medications for at least two months prior to study; No history of chronic diseases. exclusion criteria: Change in diet or physical activity patterns for any reason; Receiving Insulin during 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: receive 10 gram powdered purslane seed with 240 cc low fat yogurt and control group: use only 240 cc low fat yogurt for 5 weeks. After 2 weeks wash out period participants will move to the alternate arm. The participant 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 records once in every two weeks and physical activity levels will also be assessed by a physical activity records during the study. Main outcomes: biochemical measures including fasting plasma glucose, serum insulin, triglyceride, total-cholesterol, high density lipoprotein cholesterol (HDL-c)-, and low density lipoprotein cholesterol (LDL-c), Apo lipoprotein A and Apo lipoproteinB will be measured at the beginning and the end of each phase.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205272394N9**

Registration date: **2012-06-23, 1391/04/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-23, 1391/04/03

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4805

Email address

sjazayeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-05-01, 1391/02/12

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of portalaca olearaca on glycemic status and lipid profiles in patients with type 2 diabetes: A cross-over study

Public title

Effect of portalaca olearaca on glycemic status and lipid profiles in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non- Insulin dependent type 2 diabetic Patients; Not smoking and alcohol; Not consume supplement two weeks before the study and during the study; Not pregnant and lactation; Age 35-65 years; Not Change in dose and type of drug at least two month prior to entry 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 for any reason; Receiving 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**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran.

City

Tehran

Postal code**Approval date**

2012-04-28, 1391/02/09

Ethics committee reference number

2706/130/90/s

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**

fasting blood sugar

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

enzymatic method

2**Description**

serum Insulin

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

IRMA

3**Description**

HOMA-IR

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

formula

4**Description**

Triglyceride

Timepoint

In the beginning and at the end of each intervention phase

Method of measurement

enzymatic method

5**Description**

Total cholesterol

Timepoint

In the beginning and at the end of each intervention phase
Method of measurement
enzymatic method

6

Description
LDL
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
Friedewald formula

7

Description
HDL
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
enzymatic method

8

Description
Apo lipoprotein A
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
immunoturbidimetry

9

Description
Apo lipoprotein B
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
immunoturbidimetry

Secondary outcomes

1

Description
weight
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
scale

2

Description
Waist circumference
Timepoint
In the beginning and at the end of each intervention

phase
Method of measurement
meter

3

Description
Systolic blood pressure
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
sphygmomanometer

4

Description
Diastolic blood pressure
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
sphygmomanometer

5

Description
BMI
Timepoint
In the beginning and at the end of each intervention phase
Method of measurement
formula

Intervention groups

1

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

2

Description
Control group; 240cc/day low fat yogurt for 5 weeks
Category
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
Khoram street, Endocrinology and metabolism

Institute of Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Ghods St.,
Keshavarz Blvd, Tehran, Iran

City

Tehran

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, Tehran 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**

School of Public Health, Tehran University

Full name of responsible person

Elahe zakizadeh

Position

student of master degree of nutrition

Other areas of specialty/work**Street address**

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School of Public Health, Tehran University

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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