Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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/د

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
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Person responsible for scientific inquiries

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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