

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Esmailzadeh

###### Name of organization / entity

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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2791

###### Email address

esmailzadeh@hlth.mui.ac.ir

##### 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

190151

## 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

## 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

**Email**

e.zakizade.2010@gmail.com

**Web page address****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****Name of organization / entity**

Department of Community Nutrition, School of  
Nutrition and Food Science, Isfahan University of  
Medic

**Full name of responsible person**

Elahe Zakizadeh

**Position**

Student of master degree of nutrition

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

Hezar Jerib Ave, Isfahan University of Medical  
Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 1792 2720

**Fax****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Community Nutrition, School of  
Nutrition and Food Science, Isfahan University of  
Medic

**Full name of responsible person**

Dr Ahmad Esmaeilzadeh

**Position**

PhD of Nutrition Sciences

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

Hezar Jerib Ave, Isfahan University of Medical  
Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 1792 2720

**Fax****Email**

esmaillzadeh@hlth.mui.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Department of Community Nutrition, School of  
Nutrition and Food Science, Isfahan university of Medi

**Full name of responsible person**

Dr Ahmad Esmaeilzadeh

**Position**

Phd of Nutrition Sciences

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Hezar Jerib Ave, Isfahan University of Medical  
Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 1792 2720

**Fax****Email**

esmaillzadeh@hlth.mui.ac.ir

**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*