

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of bulk bread containing *Portulaca Oleracea* on lipid profile and glucose level in Type II Diabetes

Protocol summary

Study aim

The aim of this study is to determine the effects of bulk bread containing *Portulaca Oleracea* on lipid profile and blood sugar in patients with type 2 diabetes

Design

This study is a randomized clinical trial with parallel groups, without blinding, with 50 subjects in each group which evaluates the effect of portulaca on lipid profiles and fasting blood glucose levels in diabetic patients.

Settings and conduct

Among diabetic patients referred to diabetes clinic selected 100 patients and will be divided into two groups using quadruple blocks. The intervention group (50 patients) will receive the *Portulaca Oleracea* and the control group (50) will receive bulk without portulaca daily for 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria : age range between 30-64 years old, Body Mass Index range between 19 and 35 kg per m², diabetic patients referring to the diabetic clinic of Shahroud (or a known diagnosis of diabetes and to diagnose a physician) fasting blood glucose ≥ 125 mg / dl
Exclusion criteria: Patients receiving insulin therapy; patients with cardiovascular, renal, hepatic, hematological, hypothyroidism and convulsion diseases; patients with a history of gallstones or gallbladder surgery; patients under estrogen, steroid, beta-blocker and thiazide therapy; women planning for pregnancy; pregnant women; breast-feeding women. The use of E and C supplements of omega 3 at least 6 months before sampling, smoking and narcotics as well as those who have not been used during two weeks of training.

Intervention groups

The intervention group included 50 patients will receive bread containing portulaca (that has already been confirmed technically by its theological, physico-chemical and Sensory properties) and the control group included 50 patients receive bulk without portulaca daily for 4 weeks.

Main outcome variables

Lipid profile and blood sugar

General information

Reason for update

1. Add the duration of the intervention 2. Add more secondary outcome measures

Acronym

IRCT registration information

IRCT registration number: **IRCT20110309006010N1**

Registration date: **2019-05-18, 1398/02/28**

Registration timing: **prospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **1**

Registration date

2019-05-18, 1398/02/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

2220097 0273

Email address

delvarianzadeh@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-08, 1398/03/18

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effects of bulk bread containing Portulaca Oleracea on lipid profile and glucose level in Type II Diabetes

Public title
The effects of bread containing Portulaca Oleracea on lipid profile and blood sugar in patients with type 2 diabetes.

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range between 30-64 years old, Body Mass Index(BMI), range between 19 and 35 kg per m2, Diabetic patients referring to diabetes mellitus (known as diabetes mellitus and clinician) Fasting blood glucose $\geq$ 125mg / dl.
Exclusion criteria:
 Patients receiving insulin therapy; Patients with cardiovascular, renal, hepatic, hematological, hypothyroidism and convulsion diseases; Patients with a history of gallstones or gallbladder surgery; Patients under estrogen, steroid, beta-blocker and thiazide therapy; Women planning for pregnancy; pregnant women; breast-feeding women. The use of E and C supplements of omega 3 at least 6 months before sampling, Smoking and narcotics as well as those who have not been used during two weeks of training,

Age
From **30 years** old to **64 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
After choosing patients according to inclusion and exclusion criteria and regarding the order of entry of them to this study, the envelopes in which groups A and B are selected from random numbers are opened and subjects allocated to intervention and control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

Street address

7th of Tir square, Tehran street, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

3613773955

Approval date

2019-04-10, 1398/01/21

Ethics committee reference number

IR.SHMU.REC.1397.200

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

At the beginning of the study, the end of the second and fourth week

Method of measurement

Blood glucose level will be determined in laboratory by commercial standard kit

2

Description

Triglyceride

Timepoint

At the beginning of the study, the end of the second and eight week

Method of measurement

Blood triglyceride level will be determined in laboratory by commercial standard kit

3

Description

(HDL) High-density lipoprotein

Timepoint

At the beginning of the study, the end of the second and eighth week

Method of measurement

Blood HDL level will be determined in laboratory by commercial standard kit

4

Description

Low-density lipoprotein (LDL)

Timepoint

At the beginning of the study, the end of the second and fourth week

Method of measurement

Blood LDL level will be determined in laboratory by commercial standard kit

Secondary outcomes

1

Description

weight

Timepoint

At the beginning of the study, the end of the second and eighth week

Method of measurement

Scale

2

Description

Waist circumference

Timepoint

At the beginning of the study, the end of the second and eighth week

Method of measurement

Irresistible meter

3

Description

Systolic blood pressure

Timepoint

At the beginning of the study, the end of the second and eighth week

Method of measurement

Mercurial sphygmomanometer

4

Description

Diastolic blood pressure

Timepoint

At the beginning of the study, the end of the second and eighth week

Method of measurement

Mercurial sphygmomanometer

5

Description

Liver Enzymes (Alanine Aminotransferase, Gamma-Glutamyl Transferase, Aspartate Amino Transferase) (AST, ALT, GGT)

Timepoint

At the beginning of the study, the end of the eighth week

Method of measurement

Pars Azmon Kit

Intervention groups

1

Description

"Intervention group: " included 50 patients will receive bread containing purple(that has already been confirmed technically by its theological, physico-chemical and Sensory properties) daily for 4 weeks

Category

Other

2

Description

"Control group: " included 50 patients receive bulk without purple daily for 4 weeks

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Pasargad Clinic

Full name of responsible person

Narges Akramipour

Street address

Shahrud - 28 m Street

City

Shahrud

Province

Semnan

Postal code

3613773955

Phone

+98 23 3236 1718

Email

delvarianzadeh_mehri@yahoo.com

2

Recruitment center**Name of recruitment center**

Amam Hossian Hospital

Full name of responsible person

Fatemeh hossianpour

Street address

7 Tir SQ

City

Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 7709
Email
delvarianzadeh_mehri@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Azad University
Full name of responsible person
Mehri Delvarianzadeh
Street address
7 TirSQ
City
Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 7709
Email
delvarianzadeh_mehri@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Azad University

Proportion provided by this source

5

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mehri Delvarianzadeh
Position
Faculty instructor
Latest degree
Master
Other areas of specialty/work

Nutrition
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7 Tir SQ, Shahroud, Shahroud University of Medical Sciences
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Web page address

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mehri Delvarianzadeh
Position
Instructor
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Other areas of specialty/work
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It has not been decided at the moment and there are no

more details at the moment

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available