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 ≥ 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.

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 ≥ 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
Shahroud - 28 m Street
City
Shahroud
Province
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Postal code
3613773955
Phone
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Email
delvarianzadeh_mehri@yahoo.com

2

Recruitment center
Name of recruitment center
Amam Hossian Hospital
Full name of responsible person
Fatemeh hossianpour
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7 Tir SQ
City

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3614773947
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+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
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Phone
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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
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Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
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3614773947
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delvarianzadeh@shmu.ac.ir

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