Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Effect of Lentil sprouts on lipid profile, oxidaized low-density lipoprotein cholestrol and glycemic control in overweight and obese patients with Type2 Diabetes mellitus

Protocol summary

Summary

The present study is a clinical trial, this study don’t perform in form of blind and effects of lentil sprouts on metabolic parameters is examined in patients with Type2 Diabetes mellitus. 40 patients with Diabetes attending Diabetes, Association, Iran, Branch center will be recruited and will be randomly divided into 2 groups of intervention and control. The main inclusion criterion: patients don’t take Insulin. The main exclusion criterion: pregnancy and breast-feeding women and suffering from liver, renal, Hyperthyroidism, Hypothyroidism disease. Intervention group will receive 60-grams per day Lentil sprouts for 8 weeks. Subjects in control group will receive 1 cup of boiling water per day and continue their habitual diet without getting Lentil sprouts additionally they won’t alter their usual life style. Patients are matched in two groups according to their age, sex, medications and BMI. At the beginning of the study will be registered characters of patients. At baseline and end of the study anthropometry information (Length and, weight), the three-day food record will be gathered. Biochemical criteria including lipid profile(Total cholesterol, Triglyceride, Low density lipoprotein, High density lipoprotein), Insulin, Fasting glucose, glycated hemoglobin and insulin sensitivity, Insulin Resistance A, B and oxidized LDL-C will be measured using the appropriate techniques at baseline and endpoint of the study.

General information

Acronym

useful sprouts

IRCT registration information

IRCT registration number: **IRCT201305251640N9**
Registration date: **2013-07-06, 1392/04/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-07-06, 1392/04/15

Registrant information

Name
Parvin Mirmiran
Name of organization / entity
Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-07-01, 1392/04/10

Expected recruitment end date

2013-09-01, 1392/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Lentil sprouts on lipid profile, oxidaized low-density lipoprotein cholestrol and glycemic control in overweight and obese patients with Type2 Diabetes mellitus

Public title
Effect of lentil sprouts on blood lipid in patients with Type2 Diabetes.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: type II diabetes; lack of Insulin; being in the age range 65-30 years old and BMI=40-25. Exclusion criteria: pregnancy and breast-feeding women; liver disease, renal, hypothyroidism and hyperthyroidism disease; alcohol consumption, smoking, contraceptive pills; taking glucocorticoid drugs; consumption of lentil sprouts, supplements or multivitamins containing antioxidants during the 3 months prior to study.
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of medical sciences and health services
Street address
Golgasht St, Azadi Ave
City
Tabriz
Postal code
Approval date
2013-07-02, 1392/04/11
Ethics committee reference number
9251

Health conditions studied

1

Description of health condition studied
Diabetes Type 2
ICD-10 code
E10-14
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Total cholestrol
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
spectophotometri

2

Description
Triglycerid
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
spectophotometri

3

Description
Low density lipoprotein cholestrol
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
Frewidwald formula

4

Description
High density lipoprotein cholestrol
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
Immunotorbidometric

5

Description
Low density lipoprotein cholestrol-oxidize
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
Elaiza

6

Description
Fastig glucose
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement

oxidase

7

Description
Glycated hemoglobin(HbA1c)
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
kit

8

Description
Insulin sensivity
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
Quicki formula

9

Description
insulin resistance
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
HOMA-IR

10

Description
Hemeostasis model assessment B
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
HOMA-B formula

11

Description
Insulin
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
insulin kit

Secondary outcomes

1

Description
Length
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
Length Gauges

2

Description
weight
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
Seca scale

3

Description
bio mass index
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
W(kg)/H2 (m)

4

Description
waist
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
seca tape

5

Description
hip
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
seca tape

6

Description
physical activity
Timepoint
before and 8 weeks after intervention
Method of measurement
Physical Activity Questionnaire

7

Description
food intake
Timepoint
at baseline and after 8 weeks of intervention
Method of measurement
dietary record questionnaire

Intervention groups

1

Description
Patients in intervention group received 60 grams of lentil sprouts per day. People will take lentil sprouts into salad with lunch and dinner. Duration of intervention will be 8 weeks. Sprouts recipe lentils (brown lentils, dry): 1. lentils place into water within 24 hours; 2. at this stage, lentils are placed into a lattice; 3. after 30 hours, lentil sprouts are prepared. We keep this stuff into refrigerator.
Category
Treatment - Other

2

Description
Patients in control group will drunk one cup of boiling water a day for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Association, Iran, Center Branch
Full name of responsible person
Zahra Aslani
Street address
Sattar Khan avenue- Patris lomomba- Ramin Malekooti avenue-27
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Alireza Ostadrahimi
Street address
Golgasht St Tabriz East Azarbayjan Iran, Islamic Republic Of
City
Tabriz
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, Tabriz 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
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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