

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effects of Lentil sprouts consumption on oxidative stress and inflammatory factors of overweight and obesity patients with Typ2 diabetes mellitus.

Protocol summary

Summary

The purpose of this randomized controlled trial is to investigate the effect of lentil sprouts consumption on inflammation and oxidative stress of patients with Type 2 Diabetes mellitus. According to statistical calculations 40 patients (male and female) with Type2 Diabetes attending Diabetes, Association, Iran, Branch center will be recruited. These patients will be randomly divided into 2 groups (intervention and control). Patients not taking Insulin will be enrolled in this study. Pregnant or breast feeding women won't be participated in this study. Patients in the intervention group (20) will consume 60-grams lentil sprouts daily and those in the control group (20) will receive 1 cup of boiled water daily for 8 weeks, they will continue their habitual diet, without getting lentil sprouts. All patients were asked to maintain their usual diet and physical activity level, and not to alter their life style during the intervention. Patients will be matched in two groups according to their age, sex, medications and biomass index. At the beginning and end point of the study, medical history, 3 day food records and physical activity questionnaires will be collected and anthropometric measurements (length and, weight) will be recorded. At the beginning and end point of the study, after 14 hour overnight fasting blood samples will be taken for biochemical analysis, including inflammatory factors (High-sensitivity C - reactive protein, Tumor necrosis factor alph and adiponektin) and antioxidant indicators (total antioxidant capacity, total oxidant statue).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310274105N15**
Registration date: **2014-02-08, 1392/11/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-08, 1392/11/19

Registrant information

Name

Beit Allah Alipour

Name of organization / entity

Health & Nutrition Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

alipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical science

Expected recruitment start date

2013-10-25, 1392/08/03

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Lentil sprouts consumption on oxidative stress

and inflammatory factors of overweight and obesity patients with Typ2 diabetes mellitus.

Public title

Effect of lentil sprouts on diabetic people.

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: **40**

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, Research Institute For Endocrine Sciences, Shahid Beheshti University of Medical S

Street address

#24, Parvaneh st, Yemen st, Chamran Exp

City

tehran

Postal code

0098

Approval date

2013-10-22, 1392/07/30

Ethics committee reference number

22ECRIES92.7.30

Health conditions studied**1****Description of health condition studied**

Diabetes Type2

ICD-10 code

E10-14

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

Total Antioxidant capacity(TAC)

Timepoint

before and after 8 weeks of intervention

Method of measurement

kit, TAC

2**Description**

Total oxidant status

Timepoint

before and after 8 weeks of intervention

Method of measurement

kit, TOC

3**Description**

Adiponecktin

Timepoint

before and after 8 weeks of intervention

Method of measurement

adiponecktin kit

4**Description**

High-sensitivity C-reactive Protein

Timepoint

before and after 8 weeks of intervention

Method of measurement

hs-CRP Kit

5**Description**

Tumor necrosis factor alph

Timepoint

before and after 8 weeks of intervention

Method of measurement

TNF α kit

Secondary outcomes

empty

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

Other

2

Description

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

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Association, Iran

Full name of responsible person

Zahra aslani

Street address

#27, Ramin Malekooti st , patris lomomba st, sattarkhan EXP , Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fereidon azizi

Street address

Research Institute for Endocrine Sciences, #24 Parvaneh st, Yemen st, Chamran Exp, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Institute for Endocrine Sciences, Shahid Beheshti 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me

Full name of responsible person

Parvin Mirmiran

Position

p.h.D

Other areas of specialty/work

Street address

Research Institute For Endocrine Sciences, #24 Parvaneh st, Yemen st, Chamran Exp

City

Tehran

Postal code

Phone

+98 21 2243 2503

Fax

Email

mirmiran@endocrine.ac.ir ,
parvin.mirmiran@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

zahra aslani

Position

MSc student in Health Sciences in Nutrition

Other areas of specialty/work

Street address

Research Institute For Endocrine Sciences, #24 Parvaneh st, Yemen st, Chamran Exp Tehran

City

Tehran

Postal code

0098

Phone

+98 21 2243 2500

Fax

Email

aslani_zahra@yahoo.com

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