

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation the Effect of Nitrate in Beetroot Powder (Beta Vulgaris) on Glycemic Control and Lipid Parameters in Type 2 Diabetic Patients

Protocol summary

Study aim

Investigation of the effect of nitrate in Beetroot Powder on glycemic control and lipid parameters in type 2 diabetic patients

Design

This study is a clinical practice with control group, parallel groups, blind, and randomized. Individuals are randomly classified (based on hemoglobin concentration of glycoocyte; HbA1C) in a group of Beetroot Powder or placebo supplementation (nitrate-free beet pulp). The sample size for current study is 62 patients with type 2 diabetes.

Settings and conduct

In this study, patients with type 2 diabetes who are referred to the Iranian Diabetes Association are selected. Patients will receive supplementation or placebo for 24 weeks. At the end of the twenty-fourth week, anthropometric and blood pressure measurements are again evaluated and blood samples are taken after 12 to 14 hours of fasting. A 24-hour urine sample will be taken at the beginning and end of the study to measure the concentration of nitric oxide, creatinine, and microalbumin intake. Blood samples were taken to determine serum levels of fasting plasma glucose, hemoglobin glycosylated, insulin, serum TG, TC, LDL-c, HDL-c, thyroid tests (TSH, TT4, FT4, FT3, Anti-TPO), liver enzymes (gamma-glutamyltransferase, Alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase), Complete Blood Count (CBC). At the end, the mean of the variables in each group was compared during the study period and between the two groups.

Participants/Inclusion and exclusion criteria

Adults with type 2 diabetes

Intervention groups

Subjects in the intervention group, intake daily supplementation is about 250 mg of nitrate in the form of Beet Pulp. Subjects in the placebo group, will receive free beet pulp powder (less than 10 mg nitrate per day),

and they will receive supplemental and placebo for 24 weeks

Main outcome variables

Blood Glucose, Lipid Profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039246N1**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

Registration date

2018-05-27, 1397/03/06

Registrant information

Name

Zahra Bahadoran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

z.bahadoran@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the Effect of Nitrate in Beetroot Powder (Beta Vulgaris) on Glycemic Control and Lipid Parameters in Type 2 Diabetic Patients

Public title

Effect of Beetroot Powder on diabetes treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Non Pregnant and Non Breast Feeding Women

Exclusion criteria:

Women of childbearing age without using a safe Contraceptive method Smokers and alcohol consumers Consumers of hormonal medicines Consumers of antioxidant supplements Subjects with Heart, Liver, Lung, Chronic Kidney Disease and Thyroid Disorders Subjects with acute or chronic Inflammatory Diseases Phosphodiesterase 5 inhibitors, Migraine drugs (such as Sumatriptan), Allopurinol, Tri-rings Antidepressants, Antihistamines, Nitrate-containing drugs, Meperidine, and Sedative Medicines Consumers

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the supplementation of Nitrate in the form of Beet Pulp in the supplement and the placebo is placed in the same full capsule, it is natural that the investigator and the patient are not aware of the type of supplement received.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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

Street address

No 24, Parvaneh st., Yemen Blvd., Chamran exp.

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Postal code

19395-4763

Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR-SBMU.ENDOCRINE.REC-1395.322

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

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Blood glucose

Timepoint

At baseline of study, 4, 12 and 24 week

Method of measurement

Enzymatic colorimetry

2**Description**

Hemoglobin glycosylated

Timepoint

At baseline of study, 4, 12 and 24 week

Method of measurement

Enzymatic method

3**Description**

Triglyceride

Timepoint

At baseline of study, 4, 12 and 24 week

Method of measurement

Enzymatic colorimetry

4

Description

High density lipoprotein

Timepoint

At baseline of study, 4, 12 and 24 week

Method of measurement

Enzymatic colorimetry

5

Description

Total cholesterol

Timepoint

At baseline of study, 4, 12 and 24 week

Method of measurement

Enzymatic colorimetry

Secondary outcomes

1

Description

Weight

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Scale

2

Description

Physical activity

Timepoint

At baseline and end of study

Method of measurement

Physical activity questionnaire

3

Description

Dietary intake

Timepoint

At baseline and end of study

Method of measurement

Feed Frequency Questionnaire

4

Description

Blood pressure

Timepoint

At baseline and end of study

Method of measurement

Manometer

5

Description

Concentration of Alanine Aminotransferase

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Photometry

6

Description

Aspartate aminotransferase concentration

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Photometry

7

Description

Concentration of alkaline phosphatase

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Photometry

8

Description

Gamma glutamyltransferase concentration

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Photometry

9

Description

Thyroid Stimulating Hormon

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Electrochemical Luminescence (Laboratory Kit)

10

Description

Total thyroxine

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Electrochemical Luminescence (Laboratory Kit)

11

Description

Free thyroxine

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Electrochemical Luminescence (Laboratory Kit)

12

Description

Free triiodothyronine

Timepoint

at baseline of study, 4th,12th and 24th week

Method of measurement

Electrochemical Luminescence (Laboratory Kit)

13

Description

Urinary microalbumin

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Immunoturbidometry

14

Description

Urinary creatinine

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Jaffe kinetic method

15

Description

Nitric Oxide Metabolites

Timepoint

at baseline of study, 4th,12th and 24th week

Method of measurement

Spectrophotometric method and Grease reaction

16

Description

Waist circumference

Timepoint

At baseline of study, 4th,12th and 24th week

Method of measurement

Meter bar

Intervention groups

1

Description

Intervention group:250 mg nitrate supplement in beetroot powder

Category

Treatment - Other

2

Description

Control group: free nitrate beetroot powder(nitrate below10 mg)

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Iran diabetes society

Full name of responsible person

asad allah rajab

Street address

no.27 , Malakoti street., Patris lomomba street, Tehran, I.R. Iran.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Full name of responsible person

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azizi@erc.ac.ir

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

43

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

2

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra bahadoran

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No.2 , Arabi Ave., Velenjak, Tehran

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Intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

57

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Zahra Bahadoran

Position

Asistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific

inquiries

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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