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 glycocycele; 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 amnesotransferase), 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@endocirne.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.
City
Tehran
Province
Tehran
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

Street address
No.2 , Arabi Ave., Velenjak, Tehran

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19839-63113

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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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Position
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Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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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