Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Effect of red beetroot on metabolic factors in subjects with pre-diabetes

Protocol summary

Study aim
To examine the effect of consuming red beetroot powder on metabolic factors in people with pre-diabetes.

Design
Clinical trial with a control group and parallel design, double-blind, randomized, phase 3 on 74 patients. The WinPepi software was used for randomization.

Settings and conduct
Beetroot has the potential to be effective and therapeutic in people with pre-diabetes. People with pre-diabetes who refer to Isfahan Endocrine and Metabolism Research Center and meet the inclusion criteria will be invited to participate in this research. After obtaining informed consent, people will be asked to refer to the Endocrine and Metabolism Research Center in a fasting state of at least 8 hours during their next visit (first visit), and fasting and two-hour blood glucose samples, as well as blood and urine samples necessary for Biochemical measurements will be collected. Besides, information on anthropometrics, demographics, blood pressure, general characteristics, food intake and physical activity will be collected. At the end of week 12 (second visit), all measurements from the first visit will be repeated. During the study, the participants, the trained questioner, and the outcome examiner will be blinded to the type of intervention. For blinding, the sachets of both intervention and placebo groups will be identical in terms of shape, color, weight and other physical characteristics.

Participants/Inclusion and exclusion criteria
Inclusion criteria: people with prediabetes aged 20-80 years old. Non-Inclusion criteria: use of any anti-diabetic agent except metformin; pregnant or lactating women.

Intervention groups
Intervention: Red beetroot powder. Placebo: Rice powder

Main outcome variables
Main outcomes: 2-hour blood glucose level; fasting blood sugar; fasting insulin; hemoglobin A1C; homeostatic model assessment for insulin resistance; the quantitative insulin-sensitivity check index

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221220056876N1**
Registration date: **2023-01-02, 1401/10/12**
Registration timing: **prospective**

Last update: **2023-01-02, 1401/10/12**
Update count: **0**

Registration date
2023-01-02, 1401/10/12

Registrant information
Name
Elham Hosseini
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-01-21, 1401/11/01
Expected recruitment end date
2024-04-20, 1403/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of red beetroot on metabolic factors in subjects

with pre-diabetes

Public title
Effect of red beetroot in subjects with pre-diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-80 years old BMI 18-35 kg/m2
Exclusion criteria:
People with type 1, type 2, or gestational diabetes mellitus Use of any anti-diabetic agent except metformin Taking medication that affects glucose metabolism such as glucocorticoids, less than eight weeks before the start of the study Receiving growth hormone in less than six months before the start of the study Allergy to beetroot consumption A smoker or a history of smoking and alcohol consumption in the previous two years History of cardiovascular diseases (open heart surgery, cardiac congestion, heart failure, and uncontrolled blood pressure), liver cirrhosis/liver transplant, and/or kidney disease (CKD) History of inflammatory diseases such as rheumatoid arthritis A history of hypothyroidism or hyperthyroidism History of suffering from severe digestive diseases or mental illnesses Having often physical activity (more than 5 hours a week) Taking antioxidant supplements or hormonal treatments 4 weeks before the study Pregnant or lactating women
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the participants are randomly assigned to two groups of consuming beetroot powder (intervention) or placebo group. For randomization, the WinPepi software was used and the participants of each group (intervention and placebo) were placed in two strata (metformin users and non-users). The number of participants in each stratum was determined based on the prevalence of metformin use in prediabetic people. In the output of the software, the sequence of participants in two strata was determined, and in each stratum, the participants have been assigned to the intervention or placebo group. After randomization, the list of generated codes was deleted.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, intervention sachets will be similar to placebo sachets in terms of shape, texture, color, weight, and other physical characteristics. The intervention sachets contain beetroot powder and the placebo sachets contain rice powder, which has been prepared at the same color as the beetroot powder using an approved food color.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-08-22, 1401/05/31
Ethics committee reference number
IR.ARI.MUI.REC.1401.087

Health conditions studied

1

Description of health condition studied
Prediabetes
ICD-10 code
R73.02
ICD-10 code description
Impaired glucose tolerance (oral)

Primary outcomes

1

Description
2-hour blood glucose
Timepoint
At the baseline and after 12 weeks
Method of measurement

Enzyme calorimetry method

2

Description
Fasting blood sugar
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

3

Description
Fasting insulin
Timepoint
At the baseline and after 12 weeks
Method of measurement
The enzyme-linked immunosorbent assay

4

Description
Hemoglobin A1C
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

5

Description
Homeostatic model assessment for insulin resistance
Timepoint
At the baseline and after 12 weeks
Method of measurement
Calculated by formula

6

Description
The quantitative insulin-sensitivity check index
Timepoint
At the baseline and after 12 weeks
Method of measurement
Calculated by formula

Secondary outcomes

1

Description
Triglyceride
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

2

Description
Total cholesterol
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

3

Description
Low density lipoprotein
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

4

Description
High density lipoprotein
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

5

Description
High sensitivity-C Reactive Protein
Timepoint
At the baseline and after 12 weeks
Method of measurement
The enzyme-linked immunosorbent assay

6

Description
Glutathione
Timepoint
At the baseline and after 12 weeks
Method of measurement
The enzyme-linked immunosorbent assay

7

Description
Total antioxidant capacity
Timepoint
At the baseline and after 12 weeks
Method of measurement
The enzyme-linked immunosorbent assay

8

Description
Total oxidative stress
Timepoint
At the baseline and after 12 weeks
Method of measurement
The enzyme-linked immunosorbent assay

9

Description
Alanine transaminase
Timepoint
At the baseline and after 12 weeks

Method of measurement
Enzyme calorimetry method

10

Description
Aspartate aminotransferase
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

11

Description
Alkaline Phosphatase
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

12

Description
Gamma-glutamyltransferase
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

13

Description
The Fibrosis-4 score
Timepoint
At the baseline and after 12 weeks
Method of measurement
Calculated by formula

14

Description
Serum creatinine
Timepoint
At the baseline and after 12 weeks
Method of measurement
Kinetic Jaffe calorimetry

15

Description
Urine creatinine
Timepoint
At the baseline and after 12 weeks
Method of measurement
Kinetic Jaffe calorimetry

16

Description
Blood urea nitrogen
Timepoint
At the baseline and after 12 weeks
Method of measurement
Enzyme calorimetry method

17

Description
Urine microalbumin
Timepoint
At the baseline and after 12 weeks
Method of measurement
The enzyme-linked immunosorbent assay

Intervention groups

1

Description
Intervention group: Red beetroot powder prepared by Pak Shilan Negin Salamat private company located in Chaharmahal and Bakhtiari province, producing all kinds of fruit powder, summer vegetables, and dried vegetables, 7 grams twice a day (14 grams daily) for 12 weeks. (3 months), it is eaten with yogurt, salad, or a meal during lunch and dinner.
Category
Treatment - Other

2

Description
Control group: Rice powder prepared by Pak Shilan Negin Salamat private company located in Chaharmahal and Bakhtiari province, producing all kinds of fruit powder, summer vegetables, and dried vegetables, 7 grams twice a day (14 grams daily) for 12 weeks (3 months), it is eaten with yogurt, salad, or a meal during lunch and dinner.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Endocrine and Metabolism Research Center
Full name of responsible person
Mansour Siavash
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Web page address
https://emrc.mui.ac.ir/en/node/1120

Sponsors / Funding sources

1

Sponsor
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Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
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Fax
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research@mui.ac.ir
Web page address
https://research.mui.ac.ir/fa/sitemap
Grant name
570000056
Grant code / Reference number
240112
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
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
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Full name of responsible person
Elham Hosseini
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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Elham Hosseini
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Nutrition and Food Security Research Center, Department of Clinical Nutrition, School of Nutrition and Food Science, Isfahan University of Medical Sciences, Hezar Jerib Ave.
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data from this research can be shared after de-identifying individuals.
When the data will become available and for how long
3 months after the results are published.
To whom data/document is available
All researchers.
Under which criteria data/document could be used
Data requests will be considered only after the publication of results.
From where data/document is obtainable
The main research executor: Elham Hosseini E-mail address: hosseini@res.mui.ac.ir
What processes are involved for a request to access data/document
After the publication of the results, people intending to use data collected in this research can make their request by submitting their proposal to the main executor. If the proposal is accepted by the executor, the data will be provided to the requester.
Comments