Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of Red Beetroot (Beta vulgaris L.) consumption on insulin sensitivity index (HOMA-IR) metabolic profile, total anti-oxidant capacity, inflammation and cognitive performance in patients with type 2 diabetes

Protocol summary

Summary

This study aimed to investigate the effects of raw red beetroot on the index of insulin sensitivity, HOMA-IR, metabolic profile, antioxidant capacity, inflammation and cognitive function in patients with type 2 diabetes has been designed. Inclusion criteria included Diagnosis of type II diabetes (fasting blood sugar greater than or equal to 126 milligrams per deciliter or glucose 2 hour Post Prandial above 200 milligrams per deciliter or random blood sugar over 200), Glycated hemoglobin above 5.6% and below 8.5%, fasting glucose less than or equal to 180 Milligrams per deciliter, triglycerides less than 250 Milligrams per deciliter, body mass index less than 35, age 30 to 65 years. The exclusion criteria included insulin injections, use of tobacco and alcohol, heart disease, cardiovascular, liver and kidney disease and hypothyroidism, taking antidepressants and lack of adherence to treatment (less than 80% or less than 48 days). This study is quasi-experimental in which 45 patients 30 to 65 years with type 2 diabetes are selected based on inclusion and exclusion criteria for participation in the study. This intervention is consumption of the daily 100 grams of raw red beetroot for 8 weeks and sensitivity insulin and investigation glycated hemoglobin, fasting blood glucose, fasting insulin, lipid index, homocysteine, total antioxidant capacity, paraxonase, nitrite and cognitive function Before and after of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612262365N16**
Registration date: **2017-02-04, 1395/11/16**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-02-04, 1395/11/16

Registrant information

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Mohammad Reza Vafa
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Iran university of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Red Beetroot (Beta vulgaris L.) consumption on insulin sensitivity index (HOMA-IR) metabolic profile, total anti-oxidant capacity, inflammation and cognitive performance in patients with type 2 diabetes

Public title
The effects of raw red beetroot on hematological indices and cognitive function in patients with type 2 diabetes.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patient satisfaction; Diagnosis of type II diabetes (fasting blood glucose greater than or equal to 126 mg / dl or the2hpp l 200 mg / d, or random blood sugar over 200); HbA1c above 6.5% and below 8.5%; At least one year history of diabetes; TG <250 mg / dl; BMI< 35 kg / m^2; Age 30 to 65 years; Patients not previously participate in any research project. Exclusion criteria: insulin injections; Hyperglycemia attacks in the past year that have led to hospitalization; Use of tobacco and alcohol; The risk of cardiovascular diseases, liver and kidney and hypothyroid; Taking antidepressants; The use of any supplemental antioxidant vitamins to 3 months; being pregnant or lacting; NSAID's use of nonsteroidol anti-inflammatory drug; The emergence of any problems or sensitivity at any time during the study; Non-adherence to treatment (less than 80% or less than 48 days); The occurrence of any patient intervention; Unwillingness to cooperate; Changing drug program (injected insulin).
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
school of health, Iran university of Medical Sciences
Street address
Tehran, Hemat Express way
City
Tehran
Postal code
Approval date
2016-07-27, 1395/05/06
Ethics committee reference number
IR.IUMS.REC 1395.932132004

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HOMA-IR
Timepoint
begin and end of intervention
Method of measurement
Fasting glucose X fasting insulin formulation divided by 405

2

Description
cognitive function
Timepoint
begin and end of intervention
Method of measurement
Rating Questionnaire

3

Description
insulin
Timepoint
begin and end of intervention
Method of measurement
With the kit for insulin

4

Description
Hba1c
Timepoint
begin and end of intervention
Method of measurement
With the kit for Hba1c

5

Description
fasting blood glucose
Timepoint
begin and end of intervention

Method of measurement
With the kit for FBS

6

Description
lipid profile
Timepoint
begin and end of intervention
Method of measurement
With the kit for lipid profile

7

Description
apo A
Timepoint
begin and end of intervention
Method of measurement
With the kit for apo A

8

Description
apo B
Timepoint
begin and end of intervention
Method of measurement
With the kit for apo B

9

Description
hs-CRP
Timepoint
begin and end of intervention
Method of measurement
With the kit FOR hs-CRP

10

Description
TAC
Timepoint
begin and end of intervention
Method of measurement
With the kit FOR TAC

11

Description
Homocysteine
Timepoint
begin and end of intervention
Method of measurement
With the kit for Homocysteine

12

Description
PON-1
Timepoint
begin and end of intervention
Method of measurement
With the kit for PON-1

13

Description
nitrite
Timepoint
begin and end of intervention
Method of measurement
With the kit for nitrite

Secondary outcomes

1

Description
weight
Timepoint
begin and end of intervention
Method of measurement
Weighing scale

2

Description
blood pressure
Timepoint
begin and end of intervention
Method of measurement
Mercury Sphygmomanometer

3

Description
BMI
Timepoint
begin and end of intervention
Method of measurement
Weight in kilograms divided by the square of height in meters

4

Description
Micronutrient
Timepoint
begin and end of intervention
Method of measurement
questionnaire

5

Description
Macronutrient
Timepoint
begin and end of intervention
Method of measurement
questionnaire

6

Description
Physicsl activity

Timepoint
begin and end of intervention
Method of measurement
questionnaire

Intervention groups

1

Description
Daily consumption 100 grams raw red beetroot for 8 weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Olympic health center
Full name of responsible person
Mitra Aliahmadi
Street address
tehran
City
tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University Of Medical Sciences
Full name of responsible person
Dr seyed Ali Javad Moosavi
Street address
Hemat Experess way, Iran University of Medical Science
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
School of Health, Iran university of Medical Sciences
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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