

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Evaluate of Low Acidic Load Diet on Blood Pressure, Lipid Profiles, Blood Glucose Control Indices and Insulin Resistance in Patients with Type 2 Diabetes

Protocol summary

Study aim

The Aim of This study is Evaluating of Low Acidic Load Diet on Blood Pressure, Lipid Profiles, Blood Glucose Control Indices and Insulin Resistance in Patients with Type 2 Diabetes

Design

80 type 2 diabetic patients will be randomly divided into two groups of intervention with low acidic diet (n = 40 Individuals) and control group with normal diet (n = 40 Individuals)

Settings and conduct

The Study is being conducted in the Diabetic Clinic. Both Intervention and Control Groups are prescribed Diet for Patients with Type 2 Diabetes. Calorie Calculation is based on the Mifflin Formula. in this Formula is used of Current Weight for patients with Normal Body Mass Index and Adjusted Weight for Obese or Overweight Patients. In Obese and Overweight Patients, 500 k cal of the Calculated Energy is Reduced. The Food Exchange List varies for each Group. In Food Exchange list of the Intervention Group, Foods are ranked according to the Acidic load of the Lowest Acidic Load to High Acid Load , Respectively and High-Acid Foods have been eliminated. Food Exchange List of Control Group is the usual Food Exchange List for Diabetics. In the Intervention Group's Daily Menu, there are two Constant Snacks of very low Acidic Foods.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People Over 20 and Under 65 Years Old
People with Body Mass Index above 18.5
Exclusion criteria: Cancer, Cushing's Syndrome, Diabetic Nephropathy, Respiratory Diseases such as: Chronic Obstructive Pulmonary Disease, pregnant or breast-feeding, having Enteral or Parenteral feeding, Take Glucocorticosteroids and Insulin

Intervention groups

Diabetic Patients are divided into Intervention and

Control Groups, The Intervention Group Received a Low Acidic Diet for 12 Weeks and the Diabetic Control Group Received the Usual Diet.

Main outcome variables

Fasting Blood Sugar Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130903014551N5**

Registration date: **2020-03-22, 1399/01/03**

Registration timing: **prospective**

Last update: **2020-03-22, 1399/01/03**

Update count: **0**

Registration date

2020-03-22, 1399/01/03

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-19, 1399/01/31

Expected recruitment end date

2020-04-25, 1399/02/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluate of Low Acidic Load Diet on Blood Pressure, Lipid Profiles, Blood Glucose Control Indices and Insulin Resistance in Patients with Type 2 Diabetes

Public title

The Evaluate of Alkaline Diet on Blood Pressure, Blood Lipid, Blood Glucose in Patients with Type 2 Diabetes

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

People with Type 2 Diabetes Over 20 and Under 65 Years Old People with Type 2 Diabetes with Body Mass Index above 18.5

Exclusion criteria:

cancer Cushing's Syndrome Taking Glucocorticoids Diabetic Nephropathy Respiratory Diseases such as: Chronic Obstructive Pulmonary Disease Pregnancy and Lactation Enteral and Parenteral Feeding Use Insulin

AgeFrom **20 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Our Randomization Method is Simple and Randomization Unit is Individual We first give each person a code, then enter the code into the spss software Finally, the process of random selection of software runs.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

--

Secondary Ids

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square, Isfahan

City

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Province

Isfahan

Postal code

8174673461

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.664

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

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Fasting Blood Sugar Concentration

Timepoint

Measurement of Fasting Blood Sugar Concentration at Baseline and 12 Weeks Later

Method of measurement

Biochemical Testing to Measure Fasting Blood Sugar

Secondary outcomes**1****Description**

Serum hemoglobin A1C Concentration

Timepoint

Serum Concentration of Hemoglobin A1C Measurement at Baseline and 12 Weeks Later

Method of measurement

Biochemistry Test to Measure Serum Concentration of Hemoglobin A1C

2**Description**

Serum Concentration of Insulin

Timepoint

Measurement of Serum Insulin Concentration at Baseline

and 12 Weeks Later
Method of measurement
Biochemistry Test to Measure Serum Concentration of Insulin

3

Description
Quantitative Insulin Sensitivity Check Index(QUICKI)
Timepoint
Measurement of Insulin Sensitivity Index at Baseline and 12 Weeks Later
Method of measurement
Using the Quantitative Insulin Sensitivity Check Index(QUICKI)

4

Description
Blood Pressure
Timepoint
Measurement of Blood Pressure at Baseline and 12 Weeks Later
Method of measurement
Using Mercury Barometer

5

Description
Serum Concentration of Lipid Profile (Total Cholesterol, Low Density Lipoprotein, High Density Lipoprotein, Triglyceride)
Timepoint
Measurement of Serum Concentration of Lipid Profile (Total Cholesterol, Low Density Lipoprotein, High Density Lipoprotein, Triglyceride) at Baseline and 12 Weeks Later
Method of measurement
Biochemistry Test to Measure Serum Concentration of Lipid Profile

6

Description
Insulin Resistance Index (Homeostasis Model Assessment (HOMA))
Timepoint
Measurement of Insulin Resistance Index at Baseline and 12 Weeks Later
Method of measurement
Using the Hemostasis Model Assessment Formula (HOMA)

Intervention groups

1

Description
Intervention group: This Group is given a Diabetic Diet for 12 weeks That has been used Low-Acid Foods and has been Eliminated of High-Acid Foods in Their Diet
Category
Other

2

Description
Control group: This Group is Given a Normal Diabetic Diet.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Seyed Mohammad Hossein Rouhani
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Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square
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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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Deputy of Research & Technology of Esfahan University of Medical Sciences, Hezar Jarib Street
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Email
sh_haghjoo@med.mui.ac.ir
Web page address
<http://research.mui.ac.ir>
Grant name
Grant code / Reference number
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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Mohammad Hossein Rouhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Latest degree

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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