

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of the Mediterranean Diet on Blood Biochemical Factors in Patients with Diabetes under Drug Therapy : a Clinical Trial

Protocol summary

Summary

(1) Objective: Determining the effect of the Mediterranean diet on blood biochemical factors in patient with diabetes under drug therapy at diabetes clinic affiliated to Golestan university of medical sciences
(2) Design: Parallel clinical trial (3) Setting and conduct: Selecting 200 patients with type 2 diabetes referring to diabetes clinic of 5 Azar tertiary hospital affiliated to Golestan university of medical sciences and assigning them to two groups of intervention and control by simple random allocation. (4) Participants including major eligibility criteria: Inclusion Criteria: Having type 2 diabetes; Age range between 40 to 60 years; lack of Mediterranean diet. Exclusion Criteria: Having advanced renal, liver and heart failure; Severe physical disability; Smoking. (5) Intervention: Education of Mediterranean diet by nutritionist for 4 groups with 25 members in 2 separate sessions (8 sessions) with 2 month intervals and following- up for diet adherence by trained experts, monthly. (6) Main outcome measures (variable): Fasting Plasma Glucose (FPG), 2-hour postprandial (2 hpp), HbA1C, and lipid profile for both intervention and control groups, before initiation of the study and after every 3 months until end of the study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011131875N1**
Registration date: **2017-02-19, 1395/12/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-19, 1395/12/01

Registrant information

Name

Maryam Zahedi

Name of organization / entity

Golestan university of Medical Sciences, Gorgan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 911 177 8055

Email address

dr.zahedi-m@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences, Gorgan, Iran.

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the Mediterranean Diet on Blood Biochemical Factors in Patients with Diabetes under Drug Therapy : a Clinical Trial

Public title

Effect of the Mediterranean Diet on Blood Biochemical Factors in Patients with Diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Having type 2 diabetes; Age range between 40 to 60 years; lack of Mediterranean diet.

Exclusion Criteria: Having advanced renal, liver and heart failure; Severe physical disability; Smoking.

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Golestan University of Medical Sciences

Street address

Postal code: 4934174515, Falsafi educational campus, beginning of the Shastkola road, Gorgan, Golestan province, Iran.

City

Gorgan

Postal code

Approval date

2016-04-19, 1395/01/31

Ethics committee reference number

IR. GOUMS.REC.1395.20

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Blood biochemical Factors

Timepoint

قبل از شروع مطالعه و بعد از هر 3 ماه تا پایان مطالعه

Method of measurement

By laboratory

Secondary outcomes

1

Description

Blood pressure (BP), Body Mass Index (BMI)

Timepoint

Before initiation of the study and after every 3 months until end of the study

Method of measurement

Sphygmomanometer, Meter, and weight scale

Intervention groups

1

Description

Intervention group: Education of Mediterranean diet by nutritionist in 2 separate sessions (8 sessions, about one and half hour for each session) with 2 month intervals and Following- up for diet adherence by trained experts, monthly.

Category

Lifestyle

2

Description

Control group: there is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic of 5 Azar tertiary hospital affiliated to Golestan university of medical sciences

Full name of responsible person

Dr. Maryam Zahedi

Street address

5 Azar tertiary hospital, 5th Azar street, Gorgan, Golestan province, Iran.

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Taziki

Street address

Postal code: 4934174515, Falsafi educational campus, beginning of the Shastkola road, Gorgan, Golestan province, Iran.

City

Gorgan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Golestan 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**

Golestan University of Medical Sciences

Full name of responsible person

Dr. Maryam Zahedi

Position

Internal medicine specialist

Other areas of specialty/work**Street address**

5 Azar tertiary hospital, 5th Azar street, Gorgan, Iran.

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Person responsible for scientific inquiries

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Person responsible for updating data

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Golestan University of Medical Sciences

Full name of responsible person

Dr. Maryam Zahedi

Position

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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