

# 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.

**City**

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**Postal code****Phone**

+98 17 3235 4936

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dr.zahedi-m@goums.ac.ir

**Web page address**

## Person responsible for scientific 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**

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## Person responsible for updating data

**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**

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**City**

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**Postal code****Phone****Fax****Email****Web page address**

## 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*