

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Study of the therapeutic effect of pomegranate seed in reducing fasting blood glucose, glycosylated hemoglobin, triglyceride and blood cholesterol in patients with type 2 diabetes

Protocol summary

Study aim

Determining the therapeutic effect of pomegranate seed in reducing fasting blood glucose, glycosylated hemoglobin, triglyceride and cholesterol levels in patients with type 2 diabetes

Design

Clinical trial with control group, with parallel groups, double blind, randomized

Settings and conduct

This study was performed to control the patients' blood sugar in Yazd Diabetes Research Center by double-blind and randomized study by handing over the envelopes containing the sample or control sample to patients and selecting one of the envelopes by them and blinding the patient and the investigator.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of type 2 diabetes for one to ten years; Use of metformin and glibenclamide pills; Age of 30-60 years. Exclusion criteria: Cardiovascular disease; Renal, liver, pulmonary disorder; inflammatory and chronic gastrointestinal diseases; thyroid dysfunction; lactose intolerance; insulin injection; body mass index (BMI) > 35 kg / m²; breastfeeding and pregnancy

Intervention groups

The subjects were type 2 diabetic patients who referred to the Yazd center of diabetes research. To select the samples, the records of diabetic patients in the research center were examined, patients who had inclusion criteria of the research invited to participate in the study.

Main outcome variables

fasting blood glucose, glycosylated hemoglobin, triglyceride and cholesterol.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170125032171N2**
Registration date: **2018-05-01, 1397/02/11**
Registration timing: **retrospective**

Last update: **2018-05-01, 1397/02/11**

Update count: **0**

Registration date

2018-05-01, 1397/02/11

Registrant information

Name

Monire Seyed Hashemi

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3223 8915

Email address

m.seiedhashemi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-07, 1396/06/16

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

2017-09-07, 1396/06/16

Actual recruitment end date

2018-01-21, 1396/11/01

Trial completion date

empty

Scientific title

Study of the therapeutic effect of pomegranate seed in reducing fasting blood glucose, glycosylated hemoglobin, triglyceride and blood cholesterol in patients with type 2 diabetes

Public title

Study of the effect of pomegranate seed in diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of type 2 diabetes for between one and ten years Taking metformin and glibenclamide tablets

Exclusion criteria:

Heart disease Insulin injection Body mass index (BMI) above 35 kg / m² Breastfeeding kidney problems thyroid dysfunction pregnancy

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The two envelopes, in which they are written as sample or control, are delivered to patients and person chooses one.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and the investigator's individual and the analyst are not aware of the contents of the drug package used in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Yazd University of Medical Sciences

Street address

Bahonar field, Shahid Sadoughi University of Medical Sciences, Yazd

City

Yazd

Province

Yazd

Postal code

8951737915

Approval date

2016-09-05, 1395/06/15

Ethics committee reference number

IR.SSU.REC.1395.106

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Blood glucose

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Measuring blood sugar level in the laboratory

2

Description

Glycosylated hemoglobin

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Measuring blood sugar level in the laboratory

3

Description

Triglyceride

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Measuring blood sugar level in the laboratory

4

Description

cholesterol

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Measuring blood sugar level in the laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group receives tea bags of 5 grams of pomegranate seed powder twice a day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: This group receives tea bags of 5 grams of poly ethylene glycol twice a day for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Monire Seyed Hashemi

Street address

Bahonar Square

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Province

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Postal code

8951737915

Phone

+98 35 3728 0226

Email

diabet_center@yahoo.com

Web page address

<http://ssu.ac.ir/cms/index.php?id=1287>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Monire Seyed Hashemi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Monire Seyed Hashemi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Majid Emtiazy
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Monire Seyed Hashemi
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m.seiedhashemi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will only be available to researchers in academia and academia

Under which criteria data/document could be used

By observing ethical principles for scientific use

From where data/document is obtainable

Address: Yazd Bahonar Square, Diabetes Research Center Phone: 00983537280226 Fax: 00983537280216 email : diabet_center@yahoo.com

What processes are involved for a request to access data/document

Data will be available in the next year

Comments