Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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,doublel 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, glycosylatedhemoglobin, 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)

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+98 35 3223 8915

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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
cholestrol
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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Yazd
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Postal code
8951737915
Phone
+98 35 3728 0226
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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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Bahonar Square
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Email
diabet_center@yahoo.com
Web page address
http://ssu.ac.ir/cms/index.php?id=1287
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
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Person responsible for updating data

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Resident
Latest degree
Medical doctor
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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