Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Ziziphus jujube fruit on glycemic control and lipid profiles in people with type2 diabetes :A randomized double blinded placebo-controlled clinical trial

Protocol summary

Study aim

Determining the effectiveness of Ziziphus jujube on the improvement glycemic control and lipid profiles in people with type 2 diabetes in patients who refer to the diabetes clinic of Allameh Behlool Gonabadi Hospital.

Design

A parallel randomized double blind clinical trial with intervention and placebo group

Settings and conduct

This study will be done in Allameh Behlool Gonabadi Hospital diabetes clinic. 120 type 2 diabetes patients with inclusion criteria will be assigned to intervention and placebo group. The randomization method is block randomization. In this study patients and researchers will be blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 30-70, Patients who are diagnosed as Type 2 diabetes, Having type 2 diabetes for less than 10 years, Have a glycosylated hemoglobin (A1C) level of less than 10% Have an LDL or TG or T-Chol level above the normal range or HDL below the normal range, Informed consent able to be obtaine. Exclusion Criteria: consumption of ziziphus jujube or other herbal medicines during the last 4 weeks before the start of the study, taking anticoagulant medication, history of addiction, pregnancy and lactation.

Intervention groups

Intervention Group: Patients with type 2 diabetes that will be Recipient of standard drugs + Ziziphus jujube 40 gram daily Control Group: Patients with type 2 diabetes that will be Recipient of standard drugs + placebo

Main outcome variables

Fasting blood sugar (FBS), glycosylated hemoglobin (A1C),Total Cholesterol (Chol-T), Triglyceride (TG), Low Density Lipoprotein (LDL) and High Density Lipoprotein (HDL)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047116N2**
Registration date: **2020-11-18, 1399/08/28**
Registration timing: **prospective**

Last update: **2020-11-18, 1399/08/28**
Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Negar Shafaei bajestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6833

Email address

shafaei.n@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Ziziphus jujube fruit on glycemic control and lipid profiles in people with type2 diabetes :A randomized double blinded placebo-controlled clinical trial

Public title
The effect of Ziziphus jujube fruit on blood sugar control and lipid profiles in people with type 2 diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being between 30 and 70 years old Having a confirmed diagnosis of type 2 diabetes according to the American Diabetes Association Having type 2 diabetes for less than 10 years Have a glycosylated hemoglobin (A1C) level of less than 10% Have an LDL or TG or T-Chol level above the normal range or HDL below the normal range Having a glucometer to measure fasting blood sugar No history of allergy to ziziphus jujube fruit consumption (according to self-report) Lack of liver problems, kidney failure and cancer No consumption of ziziphus jujube or other herbal medicines during the last 4 weeks before the start of the study No history of addiction Non-pregnancy and lactation for women Lack of experience of acute and severe stress during the last 2 weeks before the start of the study No gastrointestinal symptoms after milk consumption (lactose intolerance) Having informed consent to participate in the research

Exclusion criteria:
Existence of addiction Coagulation disorders or the use of anticoagulants Consumption of other herbal medicines that affect the results of the study and its validity

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method is block randomization and block size of 4. Randomization sequence and concealment codes will de created by www.sealedenvelope.com website.

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo will be produced in a sachet with same color that Ziziphus jujube sachet is. Participants, care provider, investigator and outcome assessor are kept blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Gonabad University of Medical Science

Street address
Gonabad - Asian Roadside - Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2020-10-20, 1399/07/29

Ethics committee reference number
IR.GMU.REC.1399.088

Health conditions studied

1

Description of health condition studied
type2 diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting blood sugar (FBS)

Timepoint
before intervention and three months after intervention

Method of measurement
laboratory instruments

2

Description
low density lipoprotein (LDL)

Timepoint
before intervention and three months after intervention

Method of measurement
laboratory instruments

3

Description
Glycosylated hemoglobin (A1C)
Timepoint
before intervention and three months after intervention
Method of measurement
laboratory instruments

4

Description
high density lipoprotein (HDL)
Timepoint
before intervention and three months after intervention
Method of measurement
laboratory instruments

5

Description
total cholesterol (chol-T)
Timepoint
before intervention and three months after intervention
Method of measurement
laboratory instruments

6

Description
triglyceride (TG)
Timepoint
before intervention and three months after intervention
Method of measurement
laboratory instruments

Secondary outcomes

1

Description
BMI
Timepoint
before intervention and three months after intervention
Method of measurement
Measurement of weight and height

Intervention groups

1

Description
Intervention group: Standard Drugs + Ziziphus jujube fruit powder 20 g two times a day for three months.
Category
Treatment - Drugs

2

Description
Control group: Standard Drugs + placebo (in terms of sachet color similar to Ziziphus jujube sachet) two times a day for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Allameh Behlool Hospital
Full name of responsible person
Negar Shafaei Bajestani
Street address
Nurse St., Diabetes Clinic of Allameh Behlool Hospital, Gonabad
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5723 6833
Email
shafaei.n@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr. Shahla Khosravan
Street address
Dr.Mehdizade Blvd.
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Postal code
9691793718
Phone
+98 51 5722 3028
Email
info@gmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Negar Shafaei Bajestani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Allameh Bohlool Gonabadi Hospital, Vahdat Blvd.,Saadi St.

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Contact

Name of organization / entity

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Full name of responsible person

Negar Shafaei Bajestani

Position

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Person responsible for updating data

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Position

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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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

The researchers in university and other scientific institutes.

Under which criteria data/document could be used

Help in managing of patients.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments