

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 Behloul 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 Behloul 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 obtained. 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 be 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 Behloul Hospital

Full name of responsible person

Negar Shafaei Bajestani

Street address

Nurse St., Diabetes Clinic of Allameh Behloul Hospital, Gonabad

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

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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

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
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Person responsible for updating data

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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