

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Ziziphus fruit on lipid profile and blood glucose in type 2 diabetic patients

Protocol summary

Summary

In this clinical trial, 116 volunteers (with considering 10% loss) who have diabetes type 2 will participate by random. Participants will be divided into 2 groups, control and intervention. The intervention group will be asked to use 30 grams of Ziziphus fruit (10 grams of Ziziphus fruit in three meals to brewed). Before and after the intervention, biochemical tests such as LDL, HDL, TG, Total Chol, FBS, 2hpp, HbA1c, MDA and TAC will be taken. The height, weight and blood pressure will be measured, too. Participants will be asked not to change their physical activity, diet and drugs used during the intervention. 24-hour dietary recalls will be collected at the beginning and the end of the study days. We will follow them by phone calls or visitation. Intervention group and control group use diet. Patients will follow up for 12 weeks

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120510826N15**

Registration date: **2014-12-19, 1393/09/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-19, 1393/09/28

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 202 2817

Email address

azadnajarzadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ziziphus fruit on lipid profile and blood glucose in type 2 diabetic patients

Public title

Effect of Ziziphus fruit in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: type 2 diabetic patients with body mass index ≥ 25 ; individuals older than 30 years old; HbA1c less than 9.5; do not change in drugs during the intervention; do not use ziziphus fruit in the last 4 weeks; individuals who do not participate in another intervention; do not inject insulin. Exclusion criteria: lack of desire to continue study; have any other diseases like liver, renal and cancer disease; no use more than 30% of ziziphus fruit; individuals who suffer from diabetes more than 10 years.

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **116**

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**

Yazd Shahid Sadoghi University of Medical Sciences
Ethics Committee

Street address

Yazd, Bahonar street.

City

Yazd

Postal code**Approval date**

2014-08-09, 1393/05/18

Ethics committee reference number

17/1/95906/پ

Health conditions studied**1****Description of health condition studied**

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

2-Hour Post-Prandial Blood Glucose

Timepoint

before the intervention and 12 weeks after the

intervention

Method of measurement

blood biochemical tests

2**Description**

fasting blood sugar

Timepoint

before the intervention and 12 weeks after the
intervention

Method of measurement

blood biochemical tests

3**Description**

Hemoglobin A1c

Timepoint

before the intervention and 12 weeks after the
intervention

Method of measurement

blood biochemical tests

4**Description**

Total cholesterol

Timepoint

before the intervention and 12 weeks after the
intervention

Method of measurement

blood biochemical tests

5**Description**

Triglyceride

Timepoint

before the intervention and 12 weeks after the
intervention

Method of measurement

blood biochemical tests

6**Description**

Low density lipoprotein

Timepoint

before the intervention and 12 weeks after the
intervention

Method of measurement

blood biochemical tests

7**Description**

High density lipoprotein

Timepoint

before the intervention and 12 weeks after the
intervention

Method of measurement

blood biochemical tests

8

Description

Added at 2016-09-16: MDA

Timepoint

Added at 2016-09-16: before the intervention and 12 weeks after the intervention

Method of measurement

Added at 2016-09-16: blood biochemical tests

Secondary outcomes

1

Description

blood pressure

Timepoint

before the intervention and 12 weeks after the intervention

Method of measurement

sphygmomanometer

2

Description

weight

Timepoint

before the intervention and 12 weeks after the intervention

Method of measurement

digital scale

3

Description

BMI (Body Mass Index)

Timepoint

before the intervention and 12 weeks after the intervention

Method of measurement

scale, meter

4

Description

Added at 2016-06-30: Total antioxidant capacity.

Timepoint

Added at 2016-06-30: before the intervention and 12 weeks after the intervention

Method of measurement

Added at 2016-06-30: blood biochemical test

Intervention groups

1

Description

Intervention group: providing a diet plan with a 500 kcal/d deficit calculated from the Harris Benedict formula adjusted for sex and activity. they also use 30 gr ziziphus fruit (to brewed) daily for 12 weeks.

Category

Other

2

Description

Control group: providing a diet plan with a 500 kcal/d deficit calculated from the Harris Benedict formula adjusted for sex and activity at 12-week intervals.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Akram Barzegari

Street address

Diabetes Center, Honar Alley, Bahonar Sq

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Habib Nikookar

Street address

Vice Chancellor for Research, Yazd University of Medical Sciences, Bahonar sq., Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd Shahid Sadoughi 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

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Zeinab Yazdanpanah

Position

MSc student of Health Sciences in Nutrition

Other areas of specialty/work

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Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Nutrition Department Faculty of Health, Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Azadeh Nadjarzadeh

Position

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Person responsible for updating data

Contact

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Full name of responsible person

Zeinab Yazdanpanah

Position

MSc student of Health Sciences in Nutrition

Other areas of specialty/work

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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