Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 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

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Yazd Shahid Sadughi 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 cholestrol
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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Person responsible for scientific inquiries

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Name of organization / entity
Nutrition Department Faculty of Health, Yazd Shahid Sadoughi University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact
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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