Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effects of dried jujube (ziziphus vulgaris) on glycemic control and lipid profile in patients with type2 diabetes

Protocol summary

Summary

This randomized controlled without placebo trial is aimed to assess the effect of dried jujube on glycemic control (fasting blood sugar, fasting Insulin,Hb A1C), lipid profile (triglyceride,total cholestrol , low-density lipoprotein, high density lipoprotein, Apo A1, Apo B100), hepatic enzymes (alanine amino transferase, aspatate amino transferase) and hs-CRP on type 2 diabetes. 76 diabetic patients will be allocated randomly to equal groups: intervention (using 1 serving dried jujube=28g dried jujube) and control (without using any forms of jujube during study). During study (3 months) participants will be asked not to change their physical activity and diet. At the beginning and ending of the study, physical activity questionnaires (IPAQ) and 24-hour dietary recall questionnaires will be completed by patients and blood pressure and anthropometric measurements included weight, hight will be measured. Too, at onset and ending of study 10 milliliter venous blood will be taken after at least 10 hours fasting to conduct the mentioned laboratory tests and at the end of the study results will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604192709N37**
Registration date: **2016-05-22, 1395/03/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-22, 1395/03/02

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8862 2755

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2017-03-10, 1395/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dried jujube (ziziphus vulgaris) on glycemic control and lipid profile in patients with type2 diabetes

Public title

Effects of dried jujube on type2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:diabetic patients aged between 20-65 years; FBS more than or equal to 126 mg/dl and less than 200 mg/dl; glycosylated hemoglobin 6.5-9 percent; lack of insulin consumption; lack of history of metabolic diseases,cardiovascular disease,renal disease,tyroid ,cancer; willingness to cooperation; lack of pregnancy and lactation; no consumption of alcoholic beverages;

lack of smoking; no consumption of any drug that are metabolized in P450 cytochrome. exclusion criteria:lack of willingness to continue study; Occurrence infectious disease during studys; Occurrence pregnancy during study.

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

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
Iran University of Medical Sciences

Street address
Iran University of medical science,Hemmat highway,Tehran,Iran

City
Tehran

Postal code

Approval date
2016-01-06, 1394/10/16

Ethics committee reference number
IR.IUMS.REC.1394.9311468005

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
FBS

Timepoint
Before intervention and 3 months after intervention

Method of measurement
Enzymatic method

2

Description
HbA1C

Timepoint
Before intervention and 3 months after intervention

Method of measurement
Bronnate Affinity

3

Description
Insulin

Timepoint
Before intervention and 3 months after intervention

Method of measurement
Radio Immuno Assay(RIA)

4

Description
Insulin Sensitivity

Timepoint
Before intervention and 3 months after intervention

Method of measurement
Quantitative insulin sensitivity check index ;QUICKI

5

Description
Insulin Resistance

Timepoint
Before intervention and 3 months after intervention

Method of measurement
Homeostasis model assessment ; HOMA

6

Description
TG

Timepoint
Before intervention and 3 months after intervention

Method of measurement
Enzymatic method

7

Description
Total chol

Timepoint
Before intervention and 3 months after intervention

Method of measurement

Enzymatic method

8

Description
LDL-C
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Enzymatic method

9

Description
HDL-C
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Enzymatic method

10

Description
ApoA1
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Immunoturbidimetry method

11

Description
ApoB100
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Immunoturbidimetry method

12

Description
ALT
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Enzymatic method

13

Description
AST
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Enzymatic method

14

Description
hs-CRP
Timepoint
Before intervention and 3 months after intervention
Method of measurement
ELISA test

Secondary outcomes

1

Description
Dietary intake
Timepoint
Before intervention and 3 months after intervention
Method of measurement
24-hour recall questinnaire

2

Description
Blood Pressure
Timepoint
Before intervention and 3 months after intervention
Method of measurement
digital Barometer

3

Description
Physical Activity
Timepoint
Before intervention and 3 months after intervention
Method of measurement
international physical activity questionarre

4

Description
weight
Timepoint
Before intervention and 3 months after intervention
Method of measurement
digital scale

5

Description
BMI
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Weight(kg)/(height(m))2

Intervention groups

1

Description
Intervention group: using 1 serving dried jujube=28g dried jujube daily for 3 months.
Category
Treatment - Other

2

Description
Control group: no consumption of any forms of jujube during study (3 months)
Category

N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Zahra Irannejadniri
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Street address
Iran University of Medical Sciences, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
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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