

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 cholesterol, low-density lipoprotein, high density lipoprotein, Apo A1, Apo B100), hepatic enzymes (alanine amino transferase, aspartate 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 including weight, height 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

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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, thyroid, 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 study; 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 questionnaire

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 questionnaire

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

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farzad Shidfar

Position

Professor

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