

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of dried Zizyphus Vulgaris fruit on lipid profile, blood sugar indices and some inflammatory factors in non insulin dependent diabetes melitus patients

Protocol summary

Summary

This randomized controlled without placebo trial is aimed to assess the effectiveness of dried fruit of zizyphus vulgaris on sugar indices and lipid profile and some inflammation factors on 30 diabetic type 2 patients that are allocated randomly to control(15) and intervention(15) groups. to assess the received nutritional materials, dietary data is completed and compared for 2 days before intervention and 2 days before ending of intervention. then questionnaire of demographic factors and nutritional habits is completed and weight and height are measured. fasting blood sugar, fasting insulin ,blood sugar 2 hours after eating food , total cholesterol, low density lipo-protein cholesterol, high density lipo-protein cholesterol, triglyceride, aspartame amino transferase ,alanine amino transferase, interleukin 6, Blood urea nitrogen, Creatinin are measured in reference laboratory after 10 hours fasting. Then participants of intervention group, addition to routine treatment, will receive packages including 15 gram powder of dried zizyphus vulgaris fruit to be eaten twice daily 30 minutes before lunch and dinner each time 15 gram for 90 days. The control group will receive only routine treatment. After 3 months intervention, the variables are measured again to be compared in the intervention and control groups. At onset and ending of study ,10 milliliter venous blood is taken after at least 10 hours fasting to conduct the laboratory tests

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506192531N3**

Registration date: **2015-07-08, 1394/04/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-08, 1394/04/17

Registrant information

Name

Tahmineh Dadkhahtehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Qom University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of dried Zizyphus Vulgaris fruit on lipid profile, blood sugar indices and some inflammatory factors in non insulin dependent diabetes melitus patients

Public title

Effects of dried Zizyphus Vulgaris fruit on lipid profile,

blood sugar indices and some inflammatory factors in non insulin dependent diabetes melitus patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:History of more than 2 years NIDDM; regular reference to physician for follow up Exclusion criteria:Having diseases of kidney or liver; pregnancy; cigarette consumption;being alcoholic; insulin consumption; being exposure to sever stress during study (infection, diabetic foot,surgery, serious psychological stress); depression; consumption of psychotropic drug; experience of embarrassing complications due to ziziphus consumption; irregular consumption of ziziphus; applying other complementary treatment method simultaneously during study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done via simple lottery method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Research Chancellor for research of Qom University of Medical Sciences,N 83, Alley 1/1, Alley 4, Safashahr street, Qom

City

Qom

Postal code

37169-87366

Approval date

2015-06-11, 1394/03/21

Ethics committee reference number

IR.MUQ.REC.1394.40

Health conditions studied

1

Description of health condition studied

non insulin dependent diabetes melitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

fasting blood sugar

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

2

Description

total cholestrol

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

Secondary outcomes

1

Description

low density lipo protein to high density lipo protein ratio

Timepoint

before intervention and after 3 months intervention

Method of measurement

numerical ratio

2

Description

interlukine 6

Timepoint

before intervention and after 3 months intervention

Method of measurement

picogram per deciliter

3

Description

blood sugar 2 hours after food

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

4

Description

body mass index

Timepoint

before and after 3 months intervention

Method of measurement

numeral ratio

5

Description

fasting insuline

Timepoint

before intervention and after 3 months intervention

Method of measurement

micro unit per milliliter

6

Description

hemoglobin A1c

Timepoint

before intervention and after 3 months intervention

Method of measurement

percent

7

Description

high density lipoprotein-cholesterol

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

8

Description

low density lipoprotein-cholesterol

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

9

Description

trigeliceride

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

10

Description

Alanine Aminotransferase

Timepoint

before intervention and after 3 months intervention

Method of measurement

unit per liter

11

Description

Aspartate Aminotransferase

Timepoint

before intervention and after 3 months intervention

Method of measurement

unit per liter

12

Description

Erythrocyte sedimentation rate

Timepoint

before intervention and after 3 months intervention

Method of measurement

millimeter per hour

13

Description

c reactive protein

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per liter

14

Description

blood urea nitrogen

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

15

Description

Creatinine

Timepoint

before intervention and after 3 months intervention

Method of measurement

milligram per deciliter

16

Description

Quality of Sleep

Timepoint

before and after 3 months intervantion

Method of measurement

Pittsburgh Sleep Quality Index

Intervention groups

1

Description

Intervention group will eat 15 gram of powder of dried ziziphus fruit(total 30 gram per day) 30 minutes before lunch and dinner as they wish (for example mixed in water) for 90 days.

Category

Treatment - Other

2**Description**

Control group will receive no additional intervention

Category

N/A

Recruitment centers1**Recruitment center****Name of recruitment center**

Specialized clinic of Shahid Beheshti hospital of Qom

Full name of responsible person

Doctor Mahmood Parham

Street addressShahid Beheshti hospital, Shahid Beheshti boulevard,
Qom**City**

Qom

Sponsors / Funding sources1**Sponsor****Name of organization / entity**Vice chancellor for research of Qom University of
Medical Sciences**Full name of responsible person**

Mohammad Hosein Abdolmohammadi

Street addressN 83, Research deputy of Qom University of Medical
Sciences, Alley 1/1, Alley 4, Safashahr street, Qom**City**

Qom

Grant name**Grant code / Reference number**

94539

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

Yes

Title of funding sourceVice chancellor for research of Qom 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**

Qom University of Medical Sciences

Full name of responsible person

Tahmineh Dadkhah Tehrani

Position

Academic member/ MS Degree

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Full name of responsible person

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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