

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of date seed powder supplementation on nutritional status, metabolic, oxidative stress and inflammatory parameters in diabetes type 2 patients

Protocol summary

Study aim

Determining The effect of date seed powder supplementation on nutritional status, metabolic, oxidative stress and inflammatory parameters in diabetes type 2 patients

Design

This Randomized, three-blind study to determine the effects of date seed powder supplementation on patients with type 2 diabetes will be done. Patients were randomly divided into two groups with 21 participants based on a block randomization procedure of size six by using random allocation software (RAS). Each block involves patients with the same categories of BMI and age.

Settings and conduct

This randomized, three- blind clinical trial will be performed on T2DM patients from the Iran Diabetes Society and Hospitals of Kerman University of Medical Science.

Participants/Inclusion and exclusion criteria

Inclusion criteria included having at least 6 months of history of diabetes, age range 30 to 50 years, BMI between 25 to 30 and no weight changes during the last 3 months, no insulin therapy and use of antihypertensive drugs, propensity to take Date seed powder during the study and exclusion criteria include the use of insulin therapy, specific medications, receiving antioxidant supplements at least three months before the start of the study, a history of weight loss diet during the last 6 months or special diet, the presence of disease or Impairment, alcohol or smoking, pregnancy, lactation, being an athlete, strenuous physical activity and unwillingness to consume palm seed powder and gastrointestinal symptoms during the study.

Intervention groups

The intervention group will receive 5 grams of date seed powder daily for 8 weeks.

Main outcome variables

Glycemic markers (insulin, HbA1c, fasting blood sugar), lipid profile, anti-inflammatory markers (TNF- α , hs-CRP), oxidative stress and antioxidant markers

General information

Reason for update

No changes have been made in the protocol of the present study, and only some parameters have been added. According to the comprehensive review on registered trial, all the added parameters along with the recorded parameters were presented as a comprehensive study in this field. Unfortunately, before registering this project in the Iranian Registry of Clinical Trials due to financial constraints, some of the considered parameters were removed. Recently, due to the funding of the project via top researchers grant, researchers have re-added the deleted parameters to the project for a comprehensive study in this field.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150205020965N10**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **prospective**

Last update: **2022-06-25, 1401/04/04**

Update count: **1**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

Parvin Dehghan

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7580

Email address

dehghanp@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of date seed powder supplementation on nutritional status, metabolic, oxidative stress and inflammatory parameters in diabetes type 2 patients

Public title

The effect of date seed powder on diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Have at least 6 months of diabetes history No weight changes during the last 3 months No insulin therapy Use of blood sugar lowering drugs Tendency to consume palm kernel powder during the study Having a BMI between 25 and 35

Exclusion criteria:

Use of glucocorticoids, laxatives, anti-obesity, multivitamins, nonsteroidal anti-inflammatory drugs (NSAIDs) and antibiotics Take antioxidant supplements at least three months before the start of the study History of weight loss diet in the last 6 months or special diet Having diseases such as intestinal diseases such as inflammation of the intestines, intestinal cancer and digestive problems Having thyroid disorders, heart disease, kidney, liver, lung, infectious and other cancers treated with radiotherapy Alcohol or smoking Pregnancy, breastfeeding, being an athlete or doing strenuous physical activity

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

At baseline, eligible individuals will be matched for BMI and age according to the classification of these variables. Individuals will be randomly divided into two groups, the intervention group (n=21, receiving date seed powder) control (n=21, receiving Maltodextrin) using RAS software into 2 and 4 blocks, and will be given codes 1 and 2.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After randomization, both groups will be given date seed powder and maltodextrin that encoded in sachets weighing 2.5 g in similar packages (metalized) without the researcher intervention and coded with codes 1 and 2. Until releasing of study results, the patient, the researcher, and the data analyzer will not be aware of the assigned codes. Therefore, the study will be three-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University Of Medical Sciences, Nutrition Faculty, Attar Neyshabori Street, Golghash street.

City

Tabriz

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East Azarbaijan

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5166614711

Approval date

2020-10-16, 1399/07/25

Ethics committee reference number

IR.TBZMED.REC.1400.752

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Lipid profile (TG, TC, HDL-c)

Timepoint

At baseline and two months after the start of the study

Method of measurement

Kit

2

Description

Total antioxidant capacity

Timepoint

At baseline and two months after start of the study

Method of measurement

Kit

3

Description

Malondialdehyde

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

4

Description

Tumor Necrosis Factor(TNF)

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

5

Description

Highly sensitive C-reactive protein(hs-CRP)

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

6

Description

HbA1c

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

7

Description

Fasting glucose

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

8

Description

Fasting insulin

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

9

Description

Interleukins 4, 6, 10, 18

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

10

Description

fructosamine

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

11

Description

LPS endotoxin

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

12

Description

Pentosidine

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

13

Description

Total oxidant status (TOS)

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

14

Description

carboxymethyl lysine (CML)

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

15

Description

soluble receptor for advanced glycation end-products

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

16

Description

8-iso-prostaglandin F2 α

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

17

Description

brain-derived neurotrophic factor

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

18

Description

cortisol

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

19

Description

Tryptophan

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

20

Description

Kynurenine

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

21

Description

Adrenocorticotrophic hormone

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

22

Description

Adipokines (leptin and adiponectin)

Timepoint

At baseline and two months after start of the study

Method of measurement

enzyme-linked immunosorbent assay (ELISA) kit

23

Description

T lymphocyte (CD4 and CD8)

Timepoint

At baseline and two months after start of the study

Method of measurement

flow cytometry

24

Description

Glutathione peroxidase

Timepoint

At baseline and two months after start of the study

Method of measurement

Kit

25

Description

Superoxide dismutase

Timepoint

At baseline and two months after start of the study

Method of measurement

Kit

26

Description

Catalase

Timepoint

At baseline and two months after start of the study

Method of measurement

Kit

27

Description

Uric acid

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

28

Description

8-Hydroxy-2-deoxy-guanosine

Timepoint

At baseline and two months after start of the study

Method of measurement

kit

Secondary outcomes

1

Description

Body Mass Index (BMI)

Timepoint

At baseline and two months after baseline

Method of measurement

Scale-Meter

2

Description

Energy intake, Daily macronutrient intake (carbohydrate, protein, fat)

Timepoint

At baseline and two months after baseline

Method of measurement

questionnaire

3

Description

General Health , Sleep quality, Depression, Anxiety and Stress

Timepoint

At baseline and two months after baseline

Method of measurement

questionnaire

4

Description

Blood pressure

Timepoint

At baseline and two months after baseline

Method of measurement

manometer

Intervention groups

1

Description

Intervention group: date seed powder. This group will consume two sachets of 2.5 g of date seed powder (Flavinea Company, Iran) daily for 2 months in the morning and evening in food such as drinks or yogurt.

Category

Treatment - Other

2

Description

Control group: maltodextrin. The group will consume two sachets of 2.5 g of maltodextrin (Qinhuangdao Lihua Starch co, china) daily for two months in the morning and evening in foods such as beverages or yogurt.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital of Kerman

Full name of responsible person

Parvin Dehghan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostad Rahimi

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ostadrahimi@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Dehghan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Participant data will be presented in the article without identifiable details

When the data will become available and for how long

2022-2023

To whom data/document is available

Tabriz University of Medical Sciences

Under which criteria data/document could be used

The application must be submitted to Tabriz University of Medical Sciences. It will available if Tabriz University of Medical Sciences is allowed.

From where data/document is obtainable

Tabriz University of Medical Sciences

What processes are involved for a request to access data/document

The application must be submitted to Tabriz University of

Medical Sciences. It will available if Tabriz University of Medical Sciences is allowed.

Comments