Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 paticipants 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

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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

Province

East Azarbaijan

Postal code

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 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 F2α
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
Adrenocorticotropic 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
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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

Academic

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