

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of bitter almond gum supplement on the metabolic, inflammatory, and mental health indicators in women with type 2 diabetes

Protocol summary

Study aim

The effect of bitter almond gum supplement on the status of metabolic, inflammatory and mental health indicators in women with type 2 diabetes

Design

Clinical trial with control group, with parallel groups, Triple-blind, randomized, phase 3 on 44 patients. Randomized block software was used for randomization.

Settings and conduct

This clinical trial will be performed on patients referred to the Iranian Diabetes Association and hospitals affiliated to Tabriz University of Medical Sciences. Screened patients will be randomly divided into two groups of intervention and control. Coded supplements will be distributed to patients in similar packaging. The intervention group will received bitter almond gum and the control group will received maltodextrin for 2 months

Participants/Inclusion and exclusion criteria

Inclusion criteria were: having type 2 diabetes for more than six months, using anti-diabetic drugs and maintaining them in the period of the study, and having a normal diet and Body Mass Index of more than 25 kg/m² in the last 3 months. Type 2 diabetes was defined as a fasting plasma glucose level of more than 126 mg/dl. Patients were excluded if they had a history of gastrointestinal; cardiovascular; renal; thyroid; liver; or pancreatic diseases; if they were pregnant; smokers; lactating; consuming pre/probiotics' products; antibiotics; antacids; alcohol; anti-diarrheal; anti-inflammatory; lipid-lowering; laxatives or insulin; and finally if they had a typical fiber intake more than 30g/d

Intervention groups

The intervention group will receive a 10g/d bitter almond gum supplement for 8 weeks. The control group will receive a 10g/d maltodextrin for 8 weeks.

Main outcome variables

cytokines (IL1,6,17,10, TNF), adipokines (leptin, adiponectin, ghrelin), GLYCEMIC INDICES (HbA1c, FBS, INSULIN), Lipid profile, antioxidant/oxidative stress biomarkers, mental health, LPS, CD4/CD8

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150205020965N7**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Parvin Dehghan

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

dehghanp@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of bitter almond gum supplement on the metabolic, inflammatory, and mental health indicators in women with type 2 diabetes

Public title

The effect of bitter almond gum supplement on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 2 diabetes for more than six months according to International Diabetes Federation (fasting blood sugar level more than 126 mg/dl) Age: 30-50 y Using anti-diabetic drugs and maintaining them in the period of the study Having a normal diet Body Mass Index (BMI) more than 25 kg/m² in the last 3 months

Exclusion criteria:

Having a history of gastrointestinal Having history cardiovascular Having a history of renal Having a history of thyroid Having a history of liver; or pancreatic diseases Pregnancy and lactating Smokers Consuming prebiotic and probiotics' products

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be divided into two groups using balanced block randomization: 1) bitter almond gum consumer 2) placebo consumer. First, the quadruple Blocks and arrangement of blocks with their numbering will be determined. Then after the selection of specific blocks using a random number table and based on the number of blocks, entering the first four participants will be done. Then again, determination of the next block will be done using the random number table and this will continue until we reach the specified sample size.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Bitter almond gum and maltodextrin (Both have the same taste, color, and smell) were delivered to patients

monthly in similar cellophanes and unrecognizable without mentioning the type of supplement on the packages. In order to separate the two types of powders, in the factory, using a digital device, the code and date of production and expiration will be printed on the packages. In order for the researcher to be unaware of the patient's treatment, distribution of supplements, and placebo by another person Codes and type of supplement not known will be done. Until the study results are released, the patient, researcher, and data analyzer will not know the assigned codes.

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

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

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Tabriz

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East Azarbaijan

Postal code

5166614711

Approval date

2020-10-17, 1399/07/26

Ethics committee reference number

IR.TBZMED.REC.1399.726

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E 11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Hemoglobin A1C (HbA1c)

Timepoint

At baseline and two months after baseline

Method of measurement

Autoanalyzer

2**Description**

Lipid profile (TG, TC, HDL-c)

Timepoint

At baseline and two months after baseline

Method of measurement

Autoanalyzer

3**Description**

Tryptophan

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

4**Description**

Kynurenine

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

5**Description**

Fasting glucose

Timepoint

At baseline and two months after baseline

Method of measurement

Colorimetric Assay Kit

6**Description**

Cortisol

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza Kit

7**Description**

Glucagon-like peptide1

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

8**Description**

Fasting insulin

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

9**Description**

Carboxymethyl lysine

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

10**Description**

s-RAGE (soluble receptor for AGE)

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

11**Description**

Nitric oxide

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

12**Description**

Interleukin 6

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

13**Description**

Highly sensitive C-reactive protein(hs-CRP)

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

14**Description**

Tumor Necrosis Factor (TNF)

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

15**Description**

Interleukin 10 (IL10)

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

16

Description

Total antioxidant capacity

Timepoint

At baseline and two months after baseline

Method of measurement

Total Antioxidant Capacity (TAC) Assay Kit

17

Description

Malondialdehyde

Timepoint

At baseline and two months after baseline

Method of measurement

Colorimetric Assay Kit

18

Description

8-iso-prostaglandin F2 α (8-iso-PGF2 α)

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

19

Description

Leptin

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

20

Description

Adiponectin

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

21

Description

Ghrelin

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

22

Description

PPAR- α expression

Timepoint

At baseline and two months after baseline

Method of measurement

Polymerase chain reaction (PCR)

23

Description

Lipopolysaccharide

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

24

Description

Interleukin 17

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

25

Description

CD 8 lymphocyte

Timepoint

At baseline and two months after baseline

Method of measurement

Fucitometry

26

Description

Interleukin 1

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

27

Description

CD 4 lymphocyte

Timepoint

At baseline and two months after baseline

Method of measurement

Fucitometry

28

Description

Brain-derived Neurotrophic Factor

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

29

Description

Vascular cell adhesion molecule cell (VCAM)

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

30

Description

Plasminogen activator inhibitor (PAI)-1

Timepoint

At baseline and two months after baseline

Method of measurement

Eliza kit

Secondary outcomes

1

Description

Body Mass Index (BMI)

Timepoint

At baseline and two months after baseline

Method of measurement

Scale-Meter

2

Description

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

Timepoint

At baseline and two months after baseline

Method of measurement

Questionnaire (24-hour Dietary Recall)

3

Description

Waist circumference (WHR)

Timepoint

At baseline and two months after baseline

Method of measurement

Calculation

4

Description

Blood pressure

Timepoint

At baseline and two months after baseline

Method of measurement

Mercuric barometr

5

Description

Assessment of the body composition

Timepoint

At baseline and two months after baseline

Method of measurement

Bioelectrical impedance analysis

6

Description

Mental health

Timepoint

At baseline and two months after baseline

Method of measurement

Questionnaire (Depression Anxiety Stress Questionnaire, General Health Questionnaire)

7

Description

Appetite status

Timepoint

At baseline and two months after baseline

Method of measurement

Visual Analogue Scale Questionnaire

Intervention groups

1

Description

Intervention group: Bitter almond gum. This group will dissolve and consume two sachets (2* 5 gr) of Bitter almond gum (Payar Tejarat Zomorodin Company, Iran) twice a day, in the morning and in the evening, in lukewarm water for 2 months.

Category

Treatment - Other

2

Description

Control group: maltodextrin. This group will dissolve and consume two sachets (2*5 gr) of maltodextrin (Qinhuangdao Lihua Starch co, china) twice a day, in the morning and in the evening, in lukewarm water for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals of Tabriz University of Medical Sciences

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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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

Yes - There is 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

Not applicable

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

2020-2021

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