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; antiacids; 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
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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
Street address
Tabriz University Of Medical Sciences, Nutrition Faculty, Attar Neyshabori Street, Golghash street.
City
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 F2α (8-iso-PGF2α)
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
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Full name of responsible person
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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
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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