

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical trial of prebiotics effect on the level of perceived stress, cortisol, interferon gamma, and appetite in patients with type 2 diabetes.

Protocol summary

Study aim

Determine the effects of prebiotic supplementation on women with type 2 diabetes.

Design

This Randomized, double-blind study to determine the effects of prebiotic supplementation on women with type 2 diabetes will done. Patients were randomly divided to two groups based on block randomization procedure of size six by using random allocation software (RAS). Each block involves the patients with the same categorizes of BMI and age.

Settings and conduct

This randomized, double-blind clinical trial will performed on T2DM from the Iran Diabetes Society

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 (BMI) more than 25 kg/m² in the last 3 months. Type 2 diabetes was defined as a FPG level more than 126 mg/dl. Patients were excluded if they had 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: 10g/d resistant dextrin supplement The control group: 10g/d maltodextrin for 8 weeks.

Main outcome variables

Cortisol, Perceived Stress, IL6, IL18, TNF, Leptin, Adiponectin, Insulin, FBS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122720965N2**

Registration date: **2017-04-02, 1396/01/13**

Registration timing: **prospective**

Last update: **2018-11-30, 1397/09/09**

Update count: **2**

Registration date

2017-04-02, 1396/01/13

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

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2018-03-12, 1396/12/21

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of prebiotics effect on the level of perceived stress, cortisol, interferon gamma, and appetite in patients with type 2 diabetes.

Public title
Prebiotic effect in patients with type 2 diabetes.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having type 2 diabetes for more than six months according International Diabetes Federation (fasting blood sugar level more than 126 mg/dl) Using anti-diabetic drugs and maintaining them in the period of the study Having a normal diet and Body Mass Index (BMI) more than 25 kg/m2 in the last 3 months
Exclusion criteria:
 Having history of gastrointestinal; cardiovascular; renal; thyroid; liver; or pancreatic diseases Pregnancy and lactating Smokers Consuming prebiotic and probiotics' products Consuming antibiotics; antiacids; alcohol; anti-diarrheal; anti-inflammatory; lipid-lowering; laxatives or insulin Having a typical fiber intake more than 30g/d.

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

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
T2DM patients randomly allocated to two groups using a block randomization procedure, after matching of BMI and age.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Researcher and patients will not be aware of the type of intervention. The third person will distribute the supplement among patients.

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 Neyshabari Street, Golghash street.
City
 Tabriz
Province
 East Azarbaijan
Postal code
 5166614711
Approval date
 2010-08-20, 1389/05/29
Ethics committee reference number
 IR.TBZMED.REC.1395.949

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes
ICD-10 code
 E08
ICD-10 code description
 Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Cortisol
Timepoint
 Before start intervention and 8 weeks after intervention
Method of measurement
 Kit

2

Description
Interfron gamma
Timepoint
 Before start intervention and 8 weeks after intervention
Method of measurement
 Kit

3

Description
Perceived stress
Timepoint
 Before start intervention and 8 weeks after intervention
Method of measurement
 Perceived stress questionnaire

4

Description

IL18
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
kit

5

Description
Leptin
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
kit

6

Description
adiponectin
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
kit

7

Description
IL10
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
Kit

8

Description
insulin
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
kit

9

Description
TNF
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
KIT

10

Description
IL6
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
KIT

11

Description
FBS

Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
KIT

Secondary outcomes

1

Description
Appetite
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
Questionnaire

2

Description
GHrelin
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
kite

3

Description
quality of life
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
Questionnaire

4

Description
Tryptophan
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
kit

5

Description
Kynurenine
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
kit

6

Description
quality of sleep
Timepoint
Before start intervention and 8 weeks after intervention
Method of measurement
Questionnaire

7

Description

Alkaline phosphatase (ALP)

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

8

Description

Alanine aminotransferase (ALT)

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

Kit

9

Description

Aspartate aminotransferase (AST)

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

Kit

10

Description

total antioxidant capacity

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

11

Description

malondialdehyde

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

12

Description

soluble receptor for advanced glycation end-products

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

13

Description

total cholesterol

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

14

Description

triglyceride

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

15

Description

LDL

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

16

Description

HDL

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

17

Description

Catalase

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

18

Description

superoxide dismutase

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

19

Description

glutathione peroxidase

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

20

Description

carboxymethyl lysine

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

21

Description

Pentosidine

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

22

Description

obestatin

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

23

Description

brain-derived neurotrophic factor

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

24

Description

Endotoxin

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

25

Description

Food intake

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

Questionnaire

26

Description

Uric acid

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

27

Description

Blood urea nitrogen

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

kit

28

Description

Complete Blood Count

Timepoint

Before start intervention and 8 weeks after intervention

Method of measurement

Full Diff device

Intervention groups

1

Description

Intervention group 1 : prebiotic (Nutriose,10g/d, for 8 weeks)

Category

Treatment - Other

2

Description

Intervention group 2 (placebo): Matodextrin (matodextrin ,10g/d, for 8 weeks)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dehghan

Street address

Atar

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reserach, Tabriz University of Medical Sciences

Full name of responsible person

Parvin Dehghan

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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
Vice chancellor for reserach, 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 sience

Full name of responsible person
Dehghan

Position
PhD

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Web page address

Person responsible for scientific

inquiries

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Name of organization / entity
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Position
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Latest degree
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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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data on the baseline characteristics of subjects will be provided in the article.

When the data will become available and for how

long

2019

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