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; 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: 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)

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+98 41 3335 7580

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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 Neyshabori 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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5166614711
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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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City
Tabriz
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Email
Dehghan.nut@gmail.com

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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Person responsible for scientific inquiries

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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