Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of resitant dextrin prebiotic(nutriose FM06) supplementation on IL4, IL12 and metabolic endotoxima in the patients with type 2 diabetes

Protocol summary

Summary

The aim of this randomized, placebo-controlled trial is to investigate the effects of resistant dextrin powder on serum Levels of Interleukin 4, Interleukin 12 metabolic endotoxima in patients with type 2 diabetes. Eighty patients with type 2 diabetes that their disease was confirmed by pathological assessment will be enrolled in this study according inclusion and exclusion criteria. The participants will be assigned into control and treatment groups using permuted-blocks randomization and will be studied in Double-Blind way. Treatment group will receive 10 gram of resistant dextrin powder daily and Placebo Group will receive 10 gram of maltodextrin daily along with their breakfast and dinner meals for 8 weeks. Demographic information and 24-hour recall Questionnaire will be completed before and 8 weeks after the intervention. Blood Samples (7CC) will be taken before and after the intervention and will be kept under -70 Celsius for the relevant tests .Related biochemical measurements will be done by Elisa Kits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020520965N1**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-02-23, 1393/12/04

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

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Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences

Expected recruitment start date

2015-03-19, 1393/12/28

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of resitant dextrin prebiotic(nutriose FM06) supplementation on IL4, IL12 and metabolic endotoxima in the patients with type 2 diabetes

Public title

The effect of resitant dextrin prebiotic on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 30-50 years old; 25≤ BMI <35; having diabetes at least 6 months prior to the study; consumption of blood glucose lowering drug; fiber intake <25 g fiber/day. Exclusion criteria: Consumption of antioxidants supplements during last 3 months; using

insulin, pregnancy; lactation; acute renal disease.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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
Golbad Street, Tabriz, East Azerbayjan, Iran Tabriz East Azerbayjan

City
Tabriz

Postal code

Approval date
2015-01-12, 1393/10/22

Ethics committee reference number
93158

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Endocrine, Nutritional and metabolic diseases

Primary outcomes

1

Description
IL4

Timepoint
Before and after 8 weeks of intervention

Method of measurement
ELISA

2

Description
IL12

Timepoint
Before and after 8 weeks of intervention

Method of measurement
ELISA

3

Description
LPS

Timepoint
Before and after 8 weeks of intervention

Method of measurement
ELISA

Secondary outcomes

1

Description
BMI

Timepoint
At baseline and after 8 weeks of intervention

Method of measurement
Weight divided by Height Square

Intervention groups

1

Description
Placebo group will receive 10 gram of maltodextrin powder in the form of 5 gram packs with breakfast and dinner meals for 8 weeks. The supplement will be given monthly and during the consumption possible side effects and keeping on consumption will be monitored.

Category
Placebo

2

Description
Resistant dextrin group will receive 10 gram of Resistant dextrin powder in the form of 5 gram packs with breakfast and dinner meals for 8 weeks. The supplement will be given monthly and during the consumption possible side effects and keeping on consumption will be monitored.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetic Clinic
Full name of responsible person
Dr Parvin Dehghan
Street address
Azadi Street, Tabriz, East Azerbaijan, Islamic Republic Of Iran
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Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Dr Mohammad Reza Rashidi
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Nutrition Faculty, Tabriz University Of Medical Sciences , Attar Neyshabori Street,Tabriz, East Azerbayjan,Iran
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Tabriz
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty