

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of resistant dextrin prebiotic(nutriose FM06) supplementation on IL4, IL12 and metabolic endotoxemia 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 endotoxemia 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)

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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 resistant dextrin prebiotic(nutriose FM06) supplementation on IL4, IL12 and metabolic endotoxemia in the patients with type 2 diabetes

Public title

The effect of resistant dextrin prebiotic on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 30-50 years old; $25 \leq \text{BMI} < 35$; 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 Azerbaijan, Iran Tabriz
East Azerbaijan

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

City

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 Azerbaijan,Iran

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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

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

Contact**Name of organization / entity**

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Full name of responsible person

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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