

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study on the comparison of the effect of oligofructose-enriched inulin with maltodextrin (placebo) on some immunologic, inflammatory and anti-inflammatory factors in type 2 diabetes

Protocol summary

Summary

This randomized double blind clinical trial is designed with the goal of determining the effect of oligofructose-enriched inulin with maltodextrin on some immunologic, inflammatory and anti-inflammatory factors in type 2 diabetes. 44 patients with type 2 diabetes between the age range of 30-65 have at least 6-month history of diabetes and oral drugs lower blood sugar using and do not have liver, renal and heart diseases, will be divided randomly to two groups of 22 people into experimental or control groups with the use of the software RAS and in the form of block 6 cases. The patients in the intervention group will receive 10 g Oligofructose-enriched inulin powder /d for two months while those in the control group will receive 10g dextrin maltose/d for two months. Daily supplements will be divided into 2 portions of 5g each to be eaten during breakfast and dinner. The immunologic, inflammatory and anti-inflammatory factors will be measured before and after the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203103565N4**

Registration date: **2012-03-27, 1391/01/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-27, 1391/01/08

Registrant information

Name

Akbar Aliasgarzadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor Of Tabriz University Of Medical Sciences

Expected recruitment start date

2012-02-22, 1390/12/03

Expected recruitment end date

2012-06-23, 1391/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the comparison of the effect of oligofructose-enriched inulin with maltodextrin (placebo) on some immunologic, inflammatory and anti-inflammatory factors in type 2 diabetes

Public title

Study on the effect of oligofructose-enriched inulin in type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 30-65 years old, having diabetes at least 6 months prior to the study, consumption of blood

glucose lowering drug,. typical fiber intake <25 g fiber/d and inulin fructans intake ≤200 g fiber/d. Exclusion criteria: consumption of antioxidants supplements during last 3 months prior to the study, using insulin, pregnancy, lactation, acute renal disease,liver disease,hyperthyroidism and hypothyroidism,heart disease

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

The Research Ethics Committee Of Tabriz University
Of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht
Avenue, Tabriz, Iran

City

Tabriz

Postal code

Approval date

2012-03-12, 1390/12/22

Ethics committee reference number

9093

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

CD4/CD8,CD3,CD4,CD8,CD11b

Timepoint

Baseline,The end of the second month

Method of measurement

Flow cytometry

2

Description

IFN-γ,IL12

Timepoint

Baseline,The end of the second month

Method of measurement

Elisa

3

Description

IL4

Timepoint

Baseline,The end of the second month

Method of measurement

Elisa

Secondary outcomes

1

Description

weight,height,BMI,WHR,WC

Timepoint

Baseline,The end of second month

Method of measurement

Antropometric Methods

2

Description

TC,TG,HDL,LDL

Timepoint

Baseline,The end of second month

Method of measurement

calorimetric

3

Description

FBS,HbA1C

Timepoint

Baseline,The end of second month

Method of measurement

calorimetric

4

Description

Blood pressure

Timepoint

Baseline, The end of second month

Method of measurement

Mercury pressure measurement

Intervention groups

1

Description

Intervention group: Oligofructose-enriched inulin powder 10 g /d, divided into 2 portions of 5g each to be eaten during breakfast and dinner, for two months

Category

Treatment - Drugs

2

Description

Control group: dextrin maltose 10 g /d, divided into 2 portions of 5g each to be eaten during breakfast and dinner, for two months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Atiyeh Clinic

Full name of responsible person

Dr Akbar Ali Asgharzadeh

Street address

Atiyeh Clinic, Maralan Square, Azadi Street, Tabriz, East Azarbayjan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty Of Medicine, Tabriz University Of Medical Sciences

Full name of responsible person

Dr Akbar Ali Asgharzadeh

Street address

Faculty Of Medicine, Tabriz University Of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Faculty Of Medicine, 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

Faculty Of Medicine, Tabriz University Of Medical Sciences

Full name of responsible person

Dr Farnaz Tavakkoli

Position

Assistant Professional Internal Diseases

Other areas of specialty/work

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Person responsible for scientific inquiries

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Professor, Educational Assistant Section Of Endocrinology

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Full name of responsible person

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Position

Assistant Professional Internal Diseases

Other areas of specialty/work**Street address**

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Postal code**Phone****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