

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of Inulin prebiotic supplementation (inulin or Oligofructose-enriched inulin) on antioxidant status, metabolic, inflammatory and anti-inflammatory factors in type 2 diabetes

Protocol summary

Summary

This randomized clinical trial is designed to determine the effect of Inulin prebiotic supplementation on antioxidant status, metabolic inflammatory and anti-inflammatory factors in type 2 diabetes. A total of sixty six patients with type 2 diabetes will be randomly assigned into one of 3 groups including two 22-patient intervention groups receiving inulin powder or Oligofructose-enriched inulin powder, or control group. The patients in the intervention group will receive 10 g inulin powder /d or 10 g Oligofructose-enriched inulin powder /d for two months while those in the control group will receive 10 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 antioxidant status, metabolic, inflammatory and anti-inflammatory factors and serum lipopolysaccharide will be measured before and after the study. Also, to assessment the food intake and appetite, 24 hours food recall and appetite questionnaire will be completed before and after the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110293253N4**

Registration date: **2011-11-15, 1390/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-11-15, 1390/08/24

Registrant information

Name

Parvin Dehghan

Name of organization / entity

Tabriz MedicalScience University

Country

Iran (Islamic Republic of)

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+98 937 139 5660

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Recruitment status

Recruitment complete

Funding source

Faculty of Health & Nutrition, Tabriz University of Medical Sciences

Expected recruitment start date

2011-11-16, 1390/08/25

Expected recruitment end date

2012-02-14, 1390/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Inulin prebiotic supplementation (inulin or Oligofructose-enriched inulin) on antioxidant status, metabolic, inflammatory and anti-inflammatory factors in type 2 diabetes

Public title

The effect of Inulin prebiotic supplementation (inulin or Oligofructose-enriched inulin) on type2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 30-65 years old, 25≤ BMI <35,

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

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: **66**

Randomization (investigator's opinion)

N/A

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

Faculty of Health & Nutrition, Tabriz University of
Medical Sciences

City

tabriz

Postal code

5166614711

Approval date

2011-10-17, 1390/07/25

Ethics committee reference number

9044

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E11

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

dietary intake

Timepoint

8 weeks

Method of measurement

24 hours-food recal questionnaire

2

Description

serum antioxidant status

Timepoint

8 weeks

Method of measurement

measurement of SOD,GPX-H,TAC,MDA

3

Description

total grelin level

Timepoint

8 weeks

Method of measurement

Serum level of fasting total grelin

4

Description

lipid profiles

Timepoint

8 weeks

Method of measurement

TC, TG, LDL, HDL

5

Description

insulin level

Timepoint

8 weeks

Method of measurement

Serum level of fasting insulin

6

Description

blood glucose & HbA1c

Timepoint

8 weeks

Method of measurement

fasting blood glucose & HbA1c

7

Description

Inflammatory factors

Timepoint

8 weeks

Method of measurementHS-CRP,TNF- α ,IL-6,IFN- γ **8****Description**

Anti-Inflammatory factor

Timepoint

8 weeks

Method of measurement

IL-10

Secondary outcomes**1****Description**

Anthropometric indices

Timepoint

8 weeks

Method of measurement

Weight, Height, BMI,WB,WHR

2**Description**

appetite

Timepoint

8 weeks

Method of measurement

questionnaire

3**Description**

Lipopolysaccharide

Timepoint

8 weeks

Method of measurement

serum Lipopolysaccharide

4**Description**

blood pressure

Timepoint

8 weeks

Method of measurement

blood pressure

Intervention groups**1****Description**

Intervention group1: Inulin powder 10 g (2*5 gr)/d, divided into 2 portions of 5g each to be eaten during breakfast and dinner, for two months

Category

Treatment - Other

2**Description**

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

Category

Treatment - Other

3**Description**

Intervention group2: Oligofructose-enriched inulin powder 10 g (2*5 gr)/d, divided into 2 portions of 5g each to be eaten during breakfast and dinner, for two months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Atiyeh Clinic

Full name of responsible person

DOC Akbar Ali asgharzadeh

Street address

Maralan Square, Azadi Street, East Azarbayjan, Tabriz

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Health and Nutrition Faculty, Tabriz University of Medical sciences

Full name of responsible person

Dr. Bahram pourghasem gharghari

Street address

Health and Nutrition Faculty, 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

Health and Nutrition Faculty, 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 Health and Nutrition, Tabriz University Of
Medical Sciences

Full name of responsible person

Parvin Dehghan

Position

Ph.D.Student in Nutrition science

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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