

# 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

**Email address**

bahrampg@yahoo.com

**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 measurement**HS-CRP,TNF- $\alpha$ ,IL-6,IFN- $\gamma$ **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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**Postal code**

5166614711

**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*