

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The effect of resistant starch and nutriose FM06 supplementation on antioxidant status, metabolic and inflammatory factors in type 2 diabetes

#### Protocol summary

##### Summary

This randomized clinical trial is designed to determine the effect of resistant starch and nutriose FM06 supplementation on antioxidant status and metabolic 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 resistant starch powder or nutriose FM06 powder, or control group. The patients in the intervention group will receive 10 g resistant starch powder /d or 10 g nutriose FM06 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 and inflammatory factors 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: **IRCT201110293253N5**

Registration date: **2012-01-25, 1390/11/05**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-01-25, 1390/11/05

##### Registrant information

##### Name

Parvin Dehghan

##### Name of organization / entity

Tabriz MedicalScience University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 937 139 5660

##### Email address

bahrampg@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Nutritional Research Center Of Tabriz University Of Medical Sciences

##### Expected recruitment start date

2012-01-19, 1390/10/29

##### Expected recruitment end date

2012-03-19, 1390/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of resistant starch and nutriose FM06 supplementation on antioxidant status, metabolic and inflammatory factors in type 2 diabetes

##### Public title

The effect of resistant starch and nutriose FM06 supplementation in type 2 diabetes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age 30-65 years old,  $25 \leq \text{BMI} < 35$ , having diabetes at least 6 months prior to the study, consumption of blood glucose lowering drug,. typical fiber intake  $< 25$  g fiber/d 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)**

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

**City**

Tabriz

**Postal code****Approval date**

2012-01-14, 1390/10/24

**Ethics committee reference number**

9073

**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 week

**Method of measurement**

24 hours-food recal questionnaire

**2****Description**

serum antioxidant status

**Timepoint**

8 week

**Method of measurement**

measurement of SOD,GPX-H,TAC,MDA

**3****Description**

lipid profiles

**Timepoint**

8 week

**Method of measurement**

TC, TG, LDL, HDL

**4****Description**

insulin level

**Timepoint**

8 week

**Method of measurement**

Serum level of fasting insulin

**5****Description**

blood glucose & HbA1c

**Timepoint**

8 week

**Method of measurement**

fasting blood glucose & HbA1c

**6****Description**

Inflammatory factors

**Timepoint**

8 week

**Method of measurement**

HS-CRP,TNF- $\alpha$ ,IL-6

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

appetite

**Timepoint**

8week

**Method of measurement**

questionnaire

## 2

### **Description**

Anthropometric indices

### **Timepoint**

8week

### **Method of measurement**

Weight, Height, WB,WHR

## 3

### **Description**

blood pressure

### **Timepoint**

8 week

### **Method of measurement**

blood pressure

## **Intervention groups**

### 1

#### **Description**

Intervention group1: resistant starch 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**

Intervention group2: nutriose FM06 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

### 3

#### **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

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Atiyeh Clinic

##### **Full name of responsible person**

Dr. Bahram pourghasem gharghari

##### **Street address**

Maralan Square, Azadi Street, East Azarbayjan, Tabriz

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Nutritional Research Center, Tabriz University Of Medical Sciences

##### **Full name of responsible person**

Dr. alireza Ostadrahimi

##### **Street address**

Block B, Third Floor, Health And Nutrition Faculty, Tabriz University Of Medical Sciences , Attar Neyshabori Street,Tabriz, East Azerbaijan,Iran

##### **City**

Tabriz

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Nutritional Research Center, 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**

Nutritional Research Center, Tabriz University Of Medical Sciences

##### **Full name of responsible person**

Dr. Bahram Pourghasem gharghari

##### **Position**

PhD in Nutrition Science

##### **Other areas of specialty/work**

##### **Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Health and Nutrition Faculty, Tabriz University of Medical Sciences

**Full name of responsible person**

Parvin Dehghan

**Position**

Ph.D. Student in Nutrition Science

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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Fax****Email**

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**Web page address**

## 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*