

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- α ,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

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Web page address

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

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Position

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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