

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of simple dietary advice or a low calorie diet program supplemented with psyllium on glycemic control and inflammatory cytokines in patients with type 2 diabetes

Protocol summary

Summary

Objectives: To examine the impact of simple dietary advice or a structured low-calorie diet program on glycemic control, lipid profile and inflammatory cytokines in patients with type 2 diabetes. **Design:** This is an open randomized controlled trial with two parallel groups. Thirty-six diabetic patients will be randomized into two groups: 1-Diet program (diet group), 2- Simple nutrition advice (advice group). **Participants:** Type 2 diabetic patients that are not using insulin and have no history of diabetic retinopathy. **Setting and conduct:** Participants will be followed for 8 weeks. Fasting and 2-hour postprandial (after a standard breakfast) venous blood samples will be taken at baseline and after 8 weeks of dietary modification. Dietary compliance will be assessed through 24-hour dietary recall. **Intervention:** In the advice group, patients are given simple dietary advice on single occasion aimed to modulate carbohydrate intake (to reduce consumption of simple sugars and foods containing added simple sugars, avoidance of overeating too much refined carbohydrate and replacement with whole grain foods). In diet group, diet program will be developed for each patient based on anthropometric, dietary and physical activity assessments with energy intake deficits of 25% of total calculated energy requirements. In this group, macronutrient distribution will be 55% from carbohydrate, 25% fat, and 20% protein. In addition, patients will be instructed to ingest a tablespoon of psyllium powder dissolved in one glass of water at the evening. **Main outcome measures:** Plasma concentrations of glucose, insulin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070228742N1**

Registration date: **2016-09-30, 1395/07/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-30, 1395/07/09

Registrant information

Name

Javad Nasrollahzadeh

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-08-06, 1395/05/16

Expected recruitment end date

2016-10-08, 1395/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of simple dietary advice or a low calorie diet program supplemented with psyllium on glycemic control and inflammatory cytokines in patients with type 2

diabetes

Public title
Dietary modification and diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Type 2 diabetics; body mass index< 29, Exclusion criteria: Using insulin; history of diabetic nephropathy

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Ethics Committee

Street address

Shahid Beheshti University of Medical Sciences

City

Tehran

Postal code

Approval date

2015-01-13, 1393/10/23

Ethics committee reference number

054559

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Plasma glucose and insulin

Timepoint

Baseline and after 8 weeks

Method of measurement

Colorimetry and elisa

Secondary outcomes

1

Description

Plasma lipids and inflammatory cytokines

Timepoint

Baseline and at the end of study

Method of measurement

Colorimetry and ELISA

Intervention groups

1

Description

Hypocaloric diet program plus a tablespoon psyllium powder

Category

Lifestyle

2

Description

Simple dietary advice including to reduce consumption of simple sugars and refined carbohydrates

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Clinic in Faculty of Nutrition, Shahid Beheshti University of Medical Science

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs Mashhadi Hoseini

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46, Hafezi St., Farahzadi Blvd., Shahrak Qods, Tehran, Iran.

City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

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Fax**Email****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*