Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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

Iran (Islamic Republic of)

Phone

+98 21 2236 0656

Email address

jnasrolah@razi.ac.ir

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
Hypocaloricdiet 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
Street address
46, Hafezi St., Farahzadi Blvd., Shahrak Qods, Tehran, Iran.
City
Tehran

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hamid Ghalandari
Position
MSc
Other areas of specialty/work
Street address
46, Hafezi St., Farahzadi Blvd., Shahrak Qods, Tehran, Iran.
City
Tehran
Postal code
Phone
+98 21 2237 6420
Fax
Email
ghalandarihamid@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Departement of Clinical Nutrition and Dietetics, Faculty of Nutrition Science, Shahid Beheshti Unive
Full name of responsible person
Javad Nasrollahzadeh
Position
Ph.D.
Other areas of specialty/work
Street address
46, Hafezi St., Farahzadi Blvd., Shahrak Qods, Tehran, Iran.
City
Tehran
Postal code
Phone
+98 21 2207 7424
Fax
Email
jnasrollahzadeh@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hamid Ghalandari
Position
MSc
Other areas of specialty/work
Street address
46, Hafezi St., Farahzadi Blvd., Shahrak Qods, Tehran, Iran.
City
Tehran
Postal code
Phone
+98 21 2237 6420
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