

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effect of diet therapy on Prevention of type 2 diabetes mellitus among subjects with abnormal glucose metabolism

Protocol summary

Summary

We investigated the efficacy of two types of diet with different macronutrients, on prevention or delaying the onset of type 2 diabetes in subjects with either impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). 322 subjects with prediabetes were randomly assigned to high monounsaturated fat diet (n=107), high carbohydrate diet (n=106) or control group (n=109) and followed for 2 years. For calculating daily energy requirement in subjects with BMI \geq 25 kg/m² the weight was adjusted with the use of 110 percent of the ideal body weight with no attempt for losing body weight. Control group were encouraged to follow the Food Guide Pyramid and reduce their fat intake to less than 30% of energy consumed and saturated fat to less than 10 percent of total energy. The primary outcome variable was incidence of type 2 diabetes mellitus, diagnosed by the latest American Diabetic Association criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082214901N4**

Registration date: **2014-09-01, 1393/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-01, 1393/06/10

Registrant information

Name

Zahra Vahdat Shariatpanahi

Name of organization / entity

Faculty of Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7484

Email address

z.shariatpanahi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2012-01-10, 1390/10/20

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of diet therapy on Prevention of type 2 diabetes mellitus among subjects with abnormal glucose metabolism

Public title

Prevention of type 2 diabetes mellitus by changes in diet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: adults over 20 years Exclusion criteria: diet therapy; severe physical activity; accompanying diseases such as cancer which reduce their life expectancy; receiving thiazide diuretics; receiving systemic β blockers; receiving glucocorticoids; receiving nicotinic acid; receiving weight lowering drugs

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 322

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ilam University of Medical Sciences

Street address

Banghanjab street, Ilam, Iran

City

Ilam

Postal code

Approval date

2013-10-07, 1392/07/15

Ethics committee reference number

EC/92/h/148

Health conditions studied

1

Description of health condition studied

Prediabetes

ICD-10 code

R73.0

ICD-10 code description

Abnormal glucose tolerance test

Primary outcomes

1

Description

Abnormal glucose metabolism

Timepoint

Before diet therapy

Method of measurement

Blood test

Secondary outcomes

1

Description

Incidence of diabetes

Timepoint

After 12 and 24 months

Method of measurement

Blood test

Intervention groups

1

Description

Study group 1 received high monounsaturated fat diet

Category

Prevention

2

Description

Study group2 received high carbohydrate diet

Category

Prevention

3

Description

Control group was encouraged to follow the Food Guide Pyramid

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital

Full name of responsible person

Shaahin Shahbazi

Street address

Banganjab St, Ilam University of Medical Sciences

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr Farid Jalilian

Street address

Banganjab St, Ilam

City

Ilam

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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 Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Vahdat Shariatpanahi
Position
MD, PhD in Nutrition
Other areas of specialty/work
Street address
3, Baran, West Arghavan, Farahzadi Blvd, Shahrak Qods
City
Tehran
Postal code
Phone
+98 21 2235 7484
Fax
Email
nutritiondata@yahoo.com
z.shariatpanahi@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Vahdat Shariatpanahi
Position
MD. PhD in Nutrition

Other areas of specialty/work
Street address
3, Baran, West Arghavan, Farahzadi Blvd, Shahrak Qods
City
Tehran
Postal code
Phone
+98 21 2235 7484
Fax
Email
nutritiondata@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Faculty of Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Vahdat Shariatpanahi
Position
Assistant Professor
Other areas of specialty/work
Street address
3, Baran, West Arghavan, Farahzadi Blvd, Shahrak Qods
City
Tehran
Postal code
1981619573
Phone
+98 21 2235 7484
Fax
Email
nutritiondata@yahoo.comz.shariatpanahi@sbmu.ac.ir
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