Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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≥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

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Country

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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 ß 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
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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