

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of the low glycemic index-low glycemic load diet on HbA1c of Poor-Controlled over weight Type 2 Diabetics

Protocol summary

Summary

Objectives: To investigate the role of an alternative carbohydrate diet on glycemic control, we intend to explore the effect of a low glycemic load (Low GL)-high fat diet on glycemic response and also glycosylated hemoglobin (HbA1c) of poor-controlled diabetes patients.

Design: The project is "before and after" study in one group and each subject is him/her control. Inclusive and exclusive criteria: The inclusive criteria are: men and women with age of 30-60 years, BMI > 25, HbA1c > 8% and the exclusive criteria includes: patients having renal, heart, gastro-intestinal disorders, chronic disease, pregnant and nursing mothers. Setting and conduct: Hundred poorly-controlled diabetes patients, HbA1c > 8% who are referred to endocrine clinic in city of Qazvin and are consuming traditional medium carbohydrate diabetic diet will be recruited for the study. Fasting blood samples for biochemical analysis will be taken and weight and BMI will be recorded at the beginning and after a-10 week diet intervention. Patients will have their routine life style program during intervention. The mean of the data before and after intervention will be compared using paired t-test

Intervention: A low GL diet (Energy 1800-2200 kcal; total fat 36%; fat derived from olive oil and nuts 15%; carbohydrate 42%; protein 22%) will be administrated to patients for 10 weeks

Main outcome measures: Fasting blood glucose, HbA1c, triglyceride, cholesterol (LDL, HDL), Body weight, and BMI changes of patients will be measured, comparing related data of before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110057724N1**

Registration date: **2012-06-20, 1391/03/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-20, 1391/03/31

Registrant information

Name

Ahmad Afaghi

Name of organization / entity

Metabolic Diseases Research Center, Qazvin
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1336 0084

Email address

aafaghi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical
Sciences

Expected recruitment start date

2012-03-10, 1390/12/20

Expected recruitment end date

2012-07-20, 1391/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the low glycemic index-low glycemic load diet
on HbA1c of Poor-Controlled over weight Type 2
Diabetics

Public title

Effect of the low glycemic index-low glycemic load diet

on HbA1c of Poor-Controlled over weight Type 2 Diabetics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male and female patients with type 2 diabetic in age range of 30-60 (years) with HbA1c > 8% , BMI> 25 Exclusion criteria: Patients with renal; cardial and digestional and other chronic diseases; Patients with metabolic diseases (except for diabetic); Pregnant and nursing women

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences Ethic Committee

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd

City

Qazvin

Postal code

Approval date

2011-07-06, 1390/04/15

Ethics committee reference number

20/3052/3

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Type II Diabetes

Primary outcomes

1

Description

FBS

Timepoint

before and after 10 weeks intervention

Method of measurement

labratory biochemical measurement

2

Description

HbA1c

Timepoint

before and after 10 weeks intervention

Method of measurement

labratory biochemical measurement

3

Description

Weight

Timepoint

before and after 10 weeks intervention

Method of measurement

scale

4

Description

Tri glyceride and Cholesterol

Timepoint

before and after 10 weeks intervention

Method of measurement

labratory biochemical measurement

Secondary outcomes

empty

Intervention groups

1

Description

patients were treated with low glycemic load diet for 10 weeks.

Category

Treatment - Drugs

2

Description

before and after

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine Clinic of Booali Hospital

Full name of responsible person

Ahmad Afaghi

Street address

Boo-Ali Hospital, Boo-Ali St., Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Saeed Asefzadeh

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd

City

Qazvin

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Qazvin 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

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

Full name of responsible person

Ahmad Afaghi

Position

Director of Social Medicine, PhD Nutrition

Other areas of specialty/work

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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