

# 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 after10 weeks intervention

#### **Method of measurement**

labratory biochemical measurement

### **3**

#### **Description**

Weight

#### **Timepoint**

before and after10 weeks intervention

#### **Method of measurement**

scale

### **4**

#### **Description**

Tri glyceride and Cholesterol

#### **Timepoint**

before and after10 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**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

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**Position**

Director of Social Medicine, PhD Nutrition

**Other areas of specialty/work**

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## Person responsible for updating data

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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*