

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effect of high protein versus high carbohydrate intake at evening meal on glycemic control, lipid profile and oxidative stress in patients with type 2 diabetes

Protocol summary

Study aim

The aim of present study is to compare the effects of high protein versus high carbohydrate intake at evening meal on glycemic control, lipid profile and oxidative stress in patients with type 2 diabetes.

Design

This is a 10-week single blinded, randomized controlled trial. Applying block randomization, the participants will randomly assigned to either of the following three groups: Standard evening meal, High carbohydrate evening meal and High protein evening meal. Sample size was calculated to be 30 in each group.

Settings and conduct

The Participants will be followed for 10 weeks, during which they visit the specially designated clinic in Shiraz city at weeks 2, 5 and 10. Body weight and waist circumference will be measured before the intervention, at week 5 and at the end of the intervention. Furthermore fasting glucose, HbA1c, insulin, lipid profile and oxidative stress will be measured at the beginning and at the end of the intervention. Fasting glucose will be also measured at week 5. Participants will be unaware of random allocation into different groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are having type 2 diabetes; diabetes duration of 1-15 years; age of 30-65 years old; HbA1c \leq 8%; BMI 22-35 Kg/m²; not taking insulin or α glucosidase inhibitors; weight maintenance during past 3 month; not having heart, liver, kidney, thyroid, gastrointestinal and respiratory disorders or malignancies; not consuming alcohol; not being on special diets like vegan; not being pregnant or lactating.

Intervention groups

In Standard evening group, protein and carbohydrate are rather evenly distributed among meals. In High carbohydrate evening meal group, 40-45% of total carbohydrate intake is provided at dinner and evening

snack. In High protein evening meal group, 40-45% of total protein intake is at dinner and evening snack.

Main outcome variables

Hemoglobin A1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042733666N1**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **prospective**

Last update: **2019-04-01, 1398/01/12**

Update count: **1**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

Fatemeh Nouripour

Name of organization / entity

Shiraz Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellery for research of Shiraz University of Medical Sciences

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2017-10-02, 1396/07/10

Actual recruitment start date

2017-07-01, 1396/04/10

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

2018-03-17, 1396/12/26

Scientific title

Comparison of the effect of high protein versus high carbohydrate intake at evening meal on glycemic control, lipid profile and oxidative stress in patients with type 2 diabetes

Public title

The effect of diet on diabetes management

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 2 diabetes mellitus according to American Diabetes Association criteria Diabetes duration of 1-15 years Age range of 30-65 years old Hemoglobin A1c (HbA1c) less than or equal to 8% Body mass index (BMI) 22- 35 kilograms per square meter Weight maintenance (\pm 3 kg) during past 3 month Stable medications during at least past two month Willingness to participate in study

Exclusion criteria:

Not taking insulin or α glucosidase inhibitors Not having heart, liver, kidney, thyroid, gastrointestinal and respiratory disorders or malignancies Not consuming alcohol Not being on special diets like gluten free or vegan Not being pregnant or lactating

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly assigned into three groups using block randomization. Block size of 3 was used. To do this, first participant was assigned into the first group, second participant into the second group and third participant into the third group and the process was continued.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were not aware of random allocation to

different groups. Statistics specialist is also unaware of intervention each group received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

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Central building of Shiraz University of Medical Sciences, Zand st.

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Approval date

2017-04-17, 1396/01/28

Ethics committee reference number

IR.SUMS.REC.1396.7

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**

Hemoglobin A1c

Timepoint

The beginning and the end of the study

Method of measurement

In percent by using the assay kit

Secondary outcomes**1****Description**

Serum malondialdehyde

Timepoint

The beginning and the end of the study

Method of measurement

In micromolar by using the assay kit

2

Description

Anthropometric measurements (body weight and waist circumference)

Timepoint

The beginning, middle and the end of the study

Method of measurement

By weighting scale with accuracy of 0.1 kg and measuring tape with accuracy of 0.1 cm

3

Description

Lipid profile (Triglyceride, Total cholesterol, Low density lipoprotein cholesterol, High density lipoprotein cholesterol)

Timepoint

The beginning and the end of the study

Method of measurement

In milligram per deciliter by using the assay kit

4

Description

Fasting serum insulin

Timepoint

The beginning and the end of the study

Method of measurement

In picomole per liter by using the assay kit

5

Description

Fasting serum glucose

Timepoint

The beginning of the study, the end of weeks 2 and 5, the end of the study

Method of measurement

In milligram per deciliter by using the assay kit

Intervention groups

1

Description

Intervention group: A 10-week diet with 40-45% of daily carbohydrate intake at evening meal and bedtime snack

Category

Lifestyle

2

Description

Intervention group: A 10-week diet with 40-45% of daily protein intake at evening meal and bedtime snack

Category

Lifestyle

3

Description

Control group: A standard diet with balanced distribution of carbohydrate, protein and fat throughout the day

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic

Full name of responsible person

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Recruitment center

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Fateme Nouripour
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Person responsible for updating data

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable