Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ≤ 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)
Phone
+98 71 3725 1007
Email address
nouripourf@sums.ac.ir

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 (± 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
Street address
Central building of Shiraz University of Medical Sciences, Zand st.
City
Shiraz
Province
Fars
Postal code
14336 - 71348
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 begining and the end of the stuy
Method of measurement
In percent by using the assay kit

Secondary outcomes

1

Description
Serum malondialdehyde

Timepoint
The begining 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 begining, 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 cholestrol, Low density lipoprotein cholestrol, High density lipoprotein cholestrol)
Timepoint
The begining 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 begining 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 begining 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
Fatemeh Nouripour
Street address
Namazi Square
City
Shiraz
Province
Fars
Postal code
7166776770
Phone
+98 71 3612 1000
Email
nouripourf@sums.ac.ir

2

Recruitment center
Name of recruitment center
Hakim Diabetes Clinic
Full name of responsible person
Fatemeh Nouripour
Street address
Farhang Shahr
City
Shiraz
Province
Fars
Postal code
0000000000
Phone
+98 71 3632 5816
Email
nouripourf@sums.ac.ir

3

Recruitment center
Name of recruitment center
AliAsghar Diabetes Clinic
Full name of responsible person
Fatemeh Nouripour
Street address
Meshkinfam street
City
Shiraz
Province
Fars

Postal code
0000000000
Phone
+98 71 3228 8602
Email
nouripourf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Younes Ghasemi
Street address
Central building of Shiraz University of Medical Sciences, Zand st.
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
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
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Nouripour
Position
Postgraduate student of nutrition sciences
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
School of nutrition and food sciences, Razi Blvd.
City
Siraz
Province
Fars
Postal code
7153675541
Phone
+98 71 3725 1007
Fax
Email
nouripourf@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zohreh Mazloom
Position
Professor, Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of nutrition and food sciences, Razi Blvd.
City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+98 71 3725 1007
Fax
Email
zohreh.mazloom@gmai.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Nouripour
Position
Postgraduate student of nutrition sciences
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
School of nutrition and food sciences, Razi Blvd.
City
Shiraz
Province
Fars

Postal code
7153675541
Phone
+98 71 3725 1007
Fax
Email
nouripourf@sums.ac.ir
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