Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of medical nutrition therapy on nutrient intake and glycaemic control in diabetic inpatients

Protocol summary

Study aim
The effect of medical nutrition therapy on nutrient intake and glycaemic control in diabetic inpatients
Design
In this research ,100 eligible hospitalized diabetic patients will chosen. Then participants will randomly divided into two control and intervention groups and a code will allocated to each one of them.
Settings and conduct
Intervention group will received individualized diet and control group will received routine hospital diabetic diet which is a consistent carbohydrate meal-planning . This research will done in Shiraz Namazi hospital.
Participants/Inclusion and exclusion criteria
inclusion criteria: hospitalized diabetic patients over 18 years, Complete consent form exclusion criteria: ICU patients ; pregnancy and lactation ; tube feeding and parentral feeding patients
Intervention groups
Intervention group will received individualized diet and control group will received routine hospital diabetic diet which is a consistent carbohydrate meal-planning
Main outcome variables
mean blood glucose level mean peak blood glucose level mean nadir blood glucose level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171217037916N1**
Registration date: **2017-12-25, 1396/10/04**
Registration timing: **prospective**

Last update: **2018-10-15, 1397/07/23**
Update count: **1**
Registration date
2017-12-25, 1396/10/04

Registrant information
Name
Zahra Mousavi Shirazi Fard
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3628 1540
Email address
z_mousavi@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-12-29, 1396/10/08
Expected recruitment end date
2018-03-15, 1396/12/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of medical nutrition therapy on nutrient intake and glycaemic control in diabetic inpatients

Public title
The effect of medical nutrition therapy on diabetic inpatients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalized diabetic patients over 18 years Complete consent form
Exclusion criteria:

ICU patients Pregnancy and lactation Patients with tube feeding and total parenteral feeding

Age

From **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

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

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.SUMS.REC.1395.7

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08-E11

ICD-10 code description

دیابت ملیتوس

Primary outcomes

1

Description

Mean blood glucose level

Timepoint

From beginning of the intervention 4 times a day for 4 days (end of study)

Method of measurement

Glucometer

2

Description

Mean peak blood glucose level

Timepoint

From beginning of the intervention 4 times a day for 4 days (end of study)

Method of measurement

Glucometer

3

Description

Mean nadir blood glucose level

Timepoint

From beginning of the intervention 4 times a day for 4 days (end of study)

Method of measurement

Glucometer

Secondary outcomes

1

Description

Mean calorie intake

Timepoint

From beginning of the intervention and daily for 4 (end of intervention)

Method of measurement

4 days food record

2

Description

Mean carbohydrate intake

Timepoint

From beginning of the intervention and daily for 4 (end of intervention)

Method of measurement

4 days food record

3

Description

Mean protein intake

Timepoint

From beginning of the intervention and daily for 4 (end of intervention)

Method of measurement

4 days food record

Intervention groups

1

Description
Intervention group: Participants will received individualized diet and for each participants, during 4 days intervention, four times blood glucose (before each meal and bedtime) each day using glucometer and food intake by 4 days food record will measured.
Category
Lifestyle

2

Description
Control group:Participants will received routine hospital diabetic diet which is a consistent carbohydrate meal-planning and for each participants, during 4 days intervention, four times blood glucose (before each meal and bedtime) each day using glucometer and food intake by 4 days food record will measured.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Zahra Mousavi Shirazi Fard
Street address
Namazi hospital, , Zand Street
City
Shiraz
Province
Fars
Postal code
11351 – 71937
Phone
+98 71 3628 1540
Email
shirazifard1393@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
7th floor , central building of Shiraz university of medical sciences,Zand st.
City
Shiraz
Province
Fars
Postal code
14336 - 71348
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
Zohreh Mazloom
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Nutrition and Food Sciences, Razi st.
City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+98 71372510015
Email
zohreh.mazloom@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zohreh Mazloom
Position
Professor

Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Nutrition and Food Sciences, Razi st.
City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+98 71372510015
Email
zohreh.mazloom@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Mousavi Shirazi Fard
Position
Phd student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
School of Nutrition and Food Sciences, Razi st.
City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+98 71 3725 1001
Email
shirazifard1393@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the level of blood glucose can be shared confidentially
When the data will become available and for how long
Access period will start 6 months after printing the results
To whom data/document is available
Study data will only be available to researchers working in academic institutions
Under which criteria data/document could be used
Use in meta-analysis
From where data/document is obtainable
Zahra Mousavi Shirazi Fard , 09177017412, shirazifard1393@gmail.com Dr. Zohreh Mazloom, 09171111527,zohreh.mazloom@gmail.com
What processes are involved for a request to access data/document
Providing personal information Providing occupational information Providing information about the reason for requesting data
Comments