

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 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 parenteral 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

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##### 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

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**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**

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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****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

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