

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### The effect of nutrition education on blood glucose and insulin resistance in men fasting in Kermanshah

#### Protocol summary

##### Summary

This study was aimed to assess the effect of nutrition education on the level of changes of Insulin, FBS and HOMA index in fasting individual. This was an interventional study. A total of 160 volunteer people who were decided to definitely fast during oncoming month of Ramadan were identified and selected from mosques in the city of Kermanshah. Participants were divided randomly into two groups. The intervention group was trained for proper nutrition before and during Ramadan. The two groups were matched for age and socioeconomic status. Body composition and blood parameters was measured three times: a week before Ramadan, at the end of Ramadan and one month after Ramadan. Outcome variables were FBS, Insulin and HOMA index. Inclusion criteria were male, aged 20 to 60 years and fasting and Exclusion criteria were cut fasting.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201702269856N5**

Registration date: **2017-04-29, 1396/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-04-29, 1396/02/09

##### Registrant information

###### Name

Yahya Pasdardar

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1828 1991

##### Email address

yahya.pasdardar@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2011-10-23, 1390/08/01

##### Expected recruitment end date

2012-01-21, 1390/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of nutrition education on blood glucose and insulin resistance in men fasting in Kermanshah

##### Public title

The effect of nutrition education on blood glucose and insulin resistance in men fasting in Kermanshah

##### Purpose

Diagnostic

##### Inclusion/Exclusion criteria

Inclusion criteria : male; aged 20-60 years; a complete fasting during Ramadan; the lack of underlying disease  
Exclusion criteria : cut fasting during Ramadan for any reason

##### Age

From **20 years** old to **60 years** old

##### Gender

Male

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **160**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics CommitteeKermanshah University of Medical Sciences

##### Street address

Kermanshah

##### City

Kermanshah

##### Postal code

#### Approval date

2016-03-02, 1394/12/12

#### Ethics committee reference number

KUMS.REC.1394.481

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

#### ICD-10 code

E10

#### ICD-10 code description

Insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

FBS

#### Timepoint

Before intervention, After intervention

#### Method of measurement

By getting a blood samples from the participants and measured with laboratory kits

### 2

#### Description

Insulin

#### Timepoint

Before intervention, After intervention

#### Method of measurement

By getting a blood samples from the participants and measured with laboratory kits

## Secondary outcomes

### 1

#### Description

HOMA (homeostasis model assessment)

#### Timepoint

Before intervention, After intervention

#### Method of measurement

$[FPI \text{ (mIU/L)} \times FPG \text{ (mmol/L)}] / 22.5$

## Intervention groups

### 1

#### Description

The intervention group before and during Ramadan are trained on how to proper nutrition. Nutritional science education pamphlets in simple language and approved by nutrition educators will be

#### Category

Lifestyle

### 2

#### Description

The control group received no intervention

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Public Health

##### Full name of responsible person

Dr Yahya pasdar

##### Street address

Department of Nutrition, Faculty of Public Health, Kermanshah

##### City

Kermanshah

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research of Kermanshah

University of Medical Sciences  
**Full name of responsible person**  
 Dr Behrooz Hamzeh  
**Street address**  
 Vice Chancellor for Research and Information  
 Technology Kermanshah University of Medical  
 Sciences, Shahid Beheshti Blvd., Kermanshah  
**City**  
 Kermanshah  
**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 of Kermanshah 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**  
 Kermanshah University of Medical Sciences  
**Full name of responsible person**  
 Mitra Darbandi  
**Position**  
 MSc in Epidemiology, Researcher  
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## Person responsible for scientific inquiries

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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*