

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of a low glycaemic index(LGI) diet on anthropometric measurements, glycaemia index and lipid profile in high risk pregnancy women for gestational diabetes mellitus

#### Protocol summary

##### Summary

The purpose of this study was to determine the effect of LGI on anthropometric measurements, measures of glycaemic and lipid profile in pregnant women with gestational diabetes are at high risk of a randomized clinical trial. The samples divide randomly to block method into two groups Control and intervention. 35 participant is in each group. The target population are at high risk pregnancy women for gestational diabetes mellitus. Inclusion criteria: pregnant women with age greater than 18 years and gestational age less than 16 weeks; pregnant women with BMI>27 kg/m<sup>2</sup> and Having at least one criterion of the risk factors for gestational diabetes: history of type 2 diabetes in first-degree relatives; previous history of gestational diabetes mellitus; History of birth weight more than 4 kg; Maternal age greater than 30 years. Exclusion criteria: Smoking and alcohol consumption; special diet; Specific drug consumption; diabetes; gestational diabetes mellitus; Impaired glucose tolerance; hypothyroidism; hypertension. Pregnant women in the control group receive training and regular prenatal care. Pregnant women in the intervention group were instructed to choose more foods with low-glycemic index. At the beginning and end of the study, height, weight and blood pressure and fasting Blood glucose, fasting serum insulin, total cholesterol, LDL and HDL cholesterol, triglyceride and blood glucose levels at week 24 of pregnancy, one, two and three hours after giving 100 g oral glucose be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120525368N1**  
Registration date: **2016-04-15, 1395/01/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-15, 1395/01/27

##### Registrant information

###### Name

Ziba Kojori

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3823 5689

###### Email address

stud2298300089@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2015-12-21, 1394/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of a low glycaemic index(LGI) diet on anthropometric measurements, glycaemia index and lipid profile in high risk pregnancy women for gestational

diabetes mellitus

## Public title

Effect of diet on prevention of gestational diabetes mellitus

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with age greater than 18 years and gestational age less than 16 weeks; pregnant women with BMI>27 kg/m<sup>2</sup> and Having at least one criterion of the risk factors for gestational diabetes: history of type 2 diabetes in first-degree relatives; previous history of gestational diabetes mellitus; History of birth weight more than 4 kg; Maternal age greater than 30 years .Exclusion criteria: Smoking and alcohol consumption; special diet; Specific drug consumption; diabetes; gestational diabetes mellitus; Impaired glucose tolerance; hypothyroidism; hyper tension

## Age

From **76 years** old to **1 year** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences, Zand Blvd

##### City

Shiraz

##### Postal code

71345-1978

#### Approval date

2015-07-12, 1394/04/21

#### Ethics committee reference number

IR.SUMS.REC.1394.60

## Health conditions studied

### 1

#### Description of health condition studied

Prevention of gestational diabetes mellitus

#### ICD-10 code

024.9

#### ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

## Primary outcomes

### 1

#### Description

Fasting blood glucose

#### Timepoint

Before intervention and two months after intervention

#### Method of measurement

Blood test and measuring fasting blood glucose

### 2

#### Description

Measure blood glucose one hour and two and three hours after feeding 100 g of glucose

#### Timepoint

Two months after intervention

#### Method of measurement

Performance OGTT

### 3

#### Description

Fasting serum insulin

#### Timepoint

Before intervention and two months after intervention

#### Method of measurement

Blood test and measuring INS

### 4

#### Description

Calculate Body Mass Index(BMI)

#### Timepoint

Before intervention

#### Method of measurement

Ratio of weight in kg to the square of height in m<sup>2</sup>

## Secondary outcomes

### 1

#### Description

Measure weight

#### Timepoint

Before intervention and two months after intervention

#### Method of measurement

Digital weighing scales

## 2

### **Description**

Measure height

### **Timepoint**

Before intervention and two months after intervention

### **Method of measurement**

Measured using the wall mounted stadiometer

## 3

### **Description**

Measure systolic and diastolic blood pressure

### **Timepoint**

Before intervention and two months after intervention

### **Method of measurement**

Blood pressure measuring device

## 4

### **Description**

Assessment of dietary intake

### **Timepoint**

Before intervention , one months after and two months after intervention

### **Method of measurement**

3-Day dietary records

## 5

### **Description**

Measure total cholesterol

### **Timepoint**

Before intervention and two months after intervention

### **Method of measurement**

Blood test and measuring TC

## 6

### **Description**

Measure cholesterol LDL and HDL

### **Timepoint**

Before intervention and two months after intervention

### **Method of measurement**

Blood test and measuring LDL and HDL

## 7

### **Description**

Measure triglyceride

### **Timepoint**

Before intervention and two months after intervention

### **Method of measurement**

Blood test and measuring TG

## **Intervention groups**

### 1

#### **Description**

High risk pregnancy women for gestational diabetes mellitus in intervention group fall under low glycaemic index diet .Taught them what categories of foods low

glycaemic index and how can replace foods with a low glycaemic index. During the intervening two months.

#### **Category**

Prevention

### 2

#### **Description**

Pregnant women in the control group receive training and regular prenatal care and consultations are about food needed during pregnancy. During the intervening two months

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Hafez Hospital

##### **Full name of responsible person**

Ziba Kojori

##### **Street address**

Abiverdi Street, Hafez Hospital

##### **City**

Shiraz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr.Masum Masumpour

##### **Street address**

Shiraz University of Medical Sciences, Zand Blvd

##### **City**

Shiraz

#### **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**

*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**

School Of Nutrition and Food Science

**Full name of responsible person**

Ziba Kojori

**Position**

Postgraduate student

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

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## Person responsible for scientific inquiries

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**Fax**

## 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*