

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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/m² 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. 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

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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/m2 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 m2

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

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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