Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 leas 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
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/m2 and Having at leas 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

Other areas of specialty/work

Street address
Shiraz University of Medical Sciences, School of Nutrition and Food Sciences, Razi Blvd

City
Shiraz

Postal code
71756-78438

Phone
+98 71338235689

Fax
+98 71 3725 1001

Email
zibakojori_2015@yahoo.comk.j_zb@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Nutrition and Food Sciense

Full name of responsible person
Dr.Zohreh Mazloom

Position
PHD

Other areas of specialty/work

Street address
Shiraz University of Medical Sciences, School of Nutrition and Food Sciences, Razi Blvd

City
Shiraz

Postal code

Phone
+98 71 3626 3132

Fax
+98 71 3725 1001

Email
zohreh.mazloom@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Nutrition and Food Science

Full name of responsible person
Ziba Kojori

Position
Postgraguated student

Other areas of specialty/work

Street address
Shiraz University of Medical Sciences, School of Nutrition and Food Sciences, Razi Blvd

City
Shiraz

Postal code

Phone
+98 71 3823 5689

Fax
+98 713725001

Email
zibakojori_2015@yahoo.comk.j_zb@yahoo.com

Web page address

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