Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of soy-protein consumption on insulin resistance, inflammatory factor, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes

Protocol summary

Study aim
The aim of this study is to determine the effects of soy-protein consumption on insulin resistance, inflammatory factor, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes.

Design
Study design: Randomized controlled clinical trial.

Settings and conduct
Population and sample size: 68 patients with GDM among pregnant women of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women with GDM at 24-28 weeks' gestation and aged 18 to 40 years will be included in this study. Exclusion criteria: History of diabetes, renal impairment, chronic hypertension, hypothyroidism, eclampsia, patients with preeclampsia, intra uterine fetal death (IUFD), placenta abruption and preterm delivery and FPG more than 105 and blood glucose 2-hour postprandial more than 120 mg/dL.

Intervention groups
Intervention: Patients will be assigned to receive either soy-protein (intervention group: n=34) or the standard diet (control group: n=34).

Main outcome variables
Insulin and insulin resistance (primary outcome) and lipid, inflammatory factors and biomarkers of oxidative stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201412085623N31**
Registration date: **2014-12-19, 1393/09/28**
Registration timing: **retrospective**

Last update: **2019-09-21, 1398/06/30**
Update count: **1**

Registration date
2014-12-19, 1393/09/28

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2014-09-06, 1393/06/15

Expected recruitment end date
2014-10-03, 1393/07/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of soy-protein consumption on insulin resistance, inflammatory factor, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes

Public title
Effect of diet therapy in treatment of gestational diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged 18-40 years Diagnosed with GDM at 24-28 weeks' gestation.
Exclusion criteria:
History of diabetes Renal impairment Chronic hypertension Hypothyroidism Eclampsia Patients with preeclampsia Intra uterine fetal death (IUFD), placenta abruption and preterm delivery. FPG more than 105 and blood glucose 2-hour postprandial more than 120 mg/dL
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline and after stratification for pre-intervention BMI and weeks of gestation, subjects will be randomly divided into two groups to take either soy-protein supplements (n=34) or the standard diet (n=34).
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
Kashan University of Medical Sciences
Street address
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Approval date
2014-09-05, 1393/06/14
Ethics committee reference number
29/5/1/4229/پ

Health conditions studied

1

Description of health condition studied
Diabetes mellitus in pregnancy
ICD-10 code
O24.9
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
Insulin
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa kit

2

Description
Insulin resistance
Timepoint
Baseline and End-of-trial
Method of measurement
Calculation using HOMA formula

Secondary outcomes

1

Description
Total antioxidant capacity
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

2

Description
Triglycerides
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

3

Description
Cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

4

Description
Glutathione
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

5

Description
Malondialdehyde
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

6

Description
Hs-CRP
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

7

Description
HDL
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

8

Description
LDL cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic kit

9

Description
Nitric Oxide
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

10

Description
Newborn's weight
Timepoint
Delivery time
Method of measurement
Scale

11

Description
Newborn's head circumference
Timepoint
Delivery time
Method of measurement
Tape

12

Description
Polyhydramnios
Timepoint
End-of-trial
Method of measurement
Sonographic

13

Description
Newborn's length
Timepoint
Delivery time
Method of measurement
Tape

14

Description
Newborn's bilirubin
Timepoint
Delivery time
Method of measurement
Enzymatic kit

15

Description
Apgar score
Timepoint
Delivery time
Method of measurement
Clinical observation

16

Description
Newborns' hypoglycemia
Timepoint
After delivery
Method of measurement
Enzymatic kit

17

Description
Preterm delivery
Timepoint
After delivery
Method of measurement
Medical record

18

Description
Maternal pre-eclampsia
Timepoint
After delivery
Method of measurement
Medical record

19

Description
Maternal hospitalization
Timepoint
After delivery
Method of measurement
Medical record

20

Description
Newborns' hospitalization
Timepoint
After delivery
Method of measurement
Medical record

Intervention groups

1

Description
Intervention group: Soy-protein diet, 0.8 g/kg protein (35% animal protein, 35% soy protein, and 30% other vegetable proteins), daily for 6 weeks
Category
Treatment - Drugs

2

Description
Control group: Standard diet, 0.8 g/kg protein (70% animal and 30% vegetable proteins), daily for 6 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutritionist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available