

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

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

Isfahan

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 Rajaei Avenue, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5562 0608

Email

asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5554 2999

Email

research@kaums.ac.ir

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

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5562 0608
Email
asemi_r@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutrition PhD
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Research Center for Biochemistry and Nutrition in Metabolic Diseases, Kashan University of Medical Sciences, Kashan, I.R. Iran
City
Kashan
Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac

Web page address

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