

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effects of the Dietary Approaches to Stop Hypertension (DASH) on pregnancy outcomes in gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of the Dietary Approaches to Stop Hypertension (DASH) diet on pregnancy outcomes in gestational diabetes.

Design

Study design: Parallel clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: Among patients with gestational diabetes referred to maternity Clinic affiliated to Kashan University of Medical Sciences, 58 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. Exclusion criteria: A previous glucose intolerance/GDM diagnosis, premature preterm rupture of membrane, placenta abruption, pre-eclampsia, requiring to commence insulin therapy during intervention, complete bed rest, hypothyroidism, urinary tract infection, smoking, kidney or liver diseases, taking estrogen therapy.

Intervention groups

Intervention group: DASH diet, 6 serving vegetables, 6 serving fruits, rich in fiber and whole grains, daily for 4 weeks. Control group: Standard diet, 4 serving vegetables, 4 serving fruits, rich in protein, daily for 4 weeks.

Main outcome variables

Outcomes: Newborns' weight (primary outcomes) and other pregnancy outcomes (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201212195623N4**

Registration date: **2013-02-18, 1391/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-25, 1398/07/03**

Update count: **1**

Registration date

2013-02-18, 1391/11/30

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

2013-02-12, 1391/11/24

Expected recruitment end date

2013-03-12, 1391/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of the Dietary Approaches to Stop Hypertension (DASH) on 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:

A previous glucose intolerance/GDM diagnosis Premature preterm rupture of membrane Placenta abruption Pre-eclampsia Requiring to commence insulin therapy during intervention Complete bed rest Hypothyroidism Urinary tract infection Smoking Kidney or liver diseases Taking estrogen therapy

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: **58**

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 DASH diet or the standard diet. Randomization will be done by the use of computer-generated random numbers.

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

Ghotbe Ravandi Boulevard, Kashan

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Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2013-02-11, 1391/11/23

Ethics committee reference number

29/5/1/4139/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**

Newborns' weight

Timepoint

The first 24 h after birth

Method of measurement

Scale

Secondary outcomes**1****Description**

Newborn length

Timepoint

The first 24 h after birth

Method of measurement

Tape

2**Description**

Newborn's head circumference

Timepoint

The first 24 h after birth

Method of measurement

Tape

3**Description**

Polyhydramnios

Timepoint

After the intervention

Method of measurement

Sonography

4**Description**

Apgar score

Timepoint

Delivery time

Method of measurement

Clinical observation

Intervention groups**1****Description**

Intervention group: DASH diet, 6 serving vegetables, 6 serving fruits, rich in fiber and whole grains, daily for 4 weeks

Category

Other

2**Description**

Control group: Standard diet, 4 serving vegetables, 4 serving fruits, rich in protein, daily for 4 weeks

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Maternity Clinic, Kashan

Full name of responsible person

Zatollah Asemi

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Shahid Rajaee Avenue, Kashan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

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

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Zatollah Asemi

Position

PhD Nutrition

Latest degree

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Other areas of specialty/work

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