

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

**City**

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

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**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 Rajaei Avenue, Kashan

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**Province**

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**Email**

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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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**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

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**Phone****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**

Zatollah Asemi

**Position**

Nutrition PhD

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**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**

PhD Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province****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