

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effects of the Dietary Approaches to Stop Hypertension (DASH) on glucose tolerance and lipid profiles in gestational diabetes

Protocol summary

Study aim

Favorable effects of the Dietary Approaches to Stop Hypertension (DASH) diet on glucose tolerance and lipid profiles in gestational diabetes.

Design

Randomized clinical trial.

Settings and conduct

Among patients with GDM referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences, 78 patients will be selected according to inclusion and exclusion criteria. Fasting blood samples will be taken at baseline and 4 weeks after the intervention. At the beginning and the end of the intervention: 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion and Exclusion Criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation were included in this study. Elective subjects should not use replace treatments like Hormone or supplemental vitamin. Also those patients with preeclampsia and complete bed rest.

Intervention groups

Intervention: These patients were divided to 4 groups: intervention 1 (20 participants), control 1 (20 participants), intervention 2 (19 participants) and control 2 (19 participants).

Main outcome variables

Outcomes: Markers of HDL-cholesterol and hs-CRP (primary outcomes) and other lipid profiles and glycemic control (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201204065623N2**

Registration date: **2012-04-09, 1391/01/21**

Registration timing: **prospective**

Last update: **2019-08-15, 1398/05/24**

Update count: **1**

Registration date

2012-04-09, 1391/01/21

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

2012-04-17, 1391/01/29

Expected recruitment end date

2012-05-17, 1391/02/28

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 glucose tolerance and lipid profiles 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:
Use replace treatments like hormone Patients with preeclampsia Complete bed rest

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: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated into two treatment groups to take either DASH or control diets. Randomization will be done by the use of computer software.

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
Ravandi ghotbe avenue, Kashan

City
Kashan

Province
Isfahan

Postal code
8115187159

Approval date
2011-08-09, 1390/05/18

Ethics committee reference number
9013

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
HDL-cholesterol

Timepoint
The first and end intervention

Method of measurement
Enzymatic

2

Description
hs-CRP

Timepoint
The first and end intervention

Method of measurement
Elisa

Secondary outcomes

1

Description
Insulin resistance

Timepoint
At the beginning of the study and after 4 weeks of intervention

Method of measurement
Calculation using HOMA formula

2

Description
Insulin

Timepoint
At the beginning of the study and after 4 weeks of intervention

Method of measurement
Elisa kit

3

Description
Total cholesterol

Timepoint
At the beginning of the study and after 4 weeks of intervention

Method of measurement
Enzymatic kit

4

Description

Triglycerides

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Glutathione

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: DASH diet, 6 serving Vegetables, 6 serving fruits, rich in fiber, 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**

Naghavi clinic Kashan

Full name of responsible person

Dr Mansooreh Samimi

Street address

Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr Gholamali Hamidi

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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

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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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