

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of dietary approaches to stop hypertension (DASH) in pregnancy outcomes of pregnant women with hypertension (chronic and pregnancy)

Protocol summary

Study aim

Evaluation of diet in pregnant women Blood pressure on pregnancy outcomes.

Design

The clinical trial is divided into control and intervention groups, which are two-way blind and are performed on seventy pregnant patients with hypertension. Excel software is used to randomize it.

Settings and conduct

The present study is a double-blind clinical trial on patients with hypertension (who will be on a blood pressure-stopping diet or a normal 2-month diet) and the evaluation of patients by a physician who does not know the patient grouping and They are monitored weekly and will be performed at Imam Khomeini Hospital in Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant patient with a history of hypertension and patient satisfaction Exclusion criteria: no underlying disease and no patient cooperation

Intervention groups

Patients are randomly divided into intervention and control groups. Intervention group: Pregnant patients with high blood pressure in this group by giving (diet that stops blood pressure) during the last two months of pregnancy. Control group: Patients in this group received a high-fat, low-protein diet during the last two months of pregnancy. DASH (blood pressure suppressant) diet, which is given to patients with hypertension according to the diet of a nutritionist, which is monitored on a weekly basis.

Main outcome variables

During these 2 months, patients' blood pressure is recorded on a weekly basis and maternal and neonatal complications are assessed after delivery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050458N1**

Registration date: **2021-05-14, 1400/02/24**

Registration timing: **prospective**

Last update: **2021-05-14, 1400/02/24**

Update count: **0**

Registration date

2021-05-14, 1400/02/24

Registrant information

Name

Mahtab Shariati

Name of organization / entity

Ahvaz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 4224 8146

Email address

drmahtab64@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-15, 1400/02/25

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of dietary approaches to stop hypertension (DASH) in pregnancy outcomes of pregnant women with hypertension (chronic and pregnancy)

Public title

Evaluation of diet in pregnant women Blood pressure on pregnancy outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant patient with a history of hypertension Patient consent to participate in the study Age over 18 years

Exclusion criteria:

Existence of any underlying disease such as diabetes Patients from whom it is difficult to obtain information

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups. Assigning patients to study groups It is based on a table of random numbers and the use of a computer Accordingly, patients enter one of the two groups in the last two months of pregnancy. Random allocation sequences are performed without knowing which treatment regimen the patient is receiving.

Blinding (investigator's opinion)

Double blinded

Blinding description

Intervention (receiving a blood pressure-stopping diet or normal diet) and evaluation of patients is performed by a physician who does not know the patient grouping. Also, patients and statistical analyzers of the results will not know about patient grouping. Patients do not know how to group and do not know if the group they are in is a test or a control.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapoor University of Medical Sciences

Street address

Golestan Ave.

City

Ahwaz

Province

Khuzestan

Postal code

6135715794

Approval date

2021-02-02, 1399/11/14

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.141

Health conditions studied

1

Description of health condition studied

Chronic hypertension and Gestational

ICD-10 code

O13.9

ICD-10 code description

Gestational [pregnancy-induced] hypertension without significant proteinuria, unspecified trimester

2

Description of health condition studied

Chronic hypertension (primary)

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

High Blood Pressure

Timepoint

Before Childbirth

Method of measurement

Mercury Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Patients with hypertension in the intervention group are given by a dietitian DASH and the evaluation of patients is monitored by a doctor on a weekly basis for two months and the results are analyzed based on a questionnaire. Clinical outcomes such as preeclampsia, eclampsia, preterm delivery, placental abruption, Apgar scores in the first and fifth minutes, neonatal weight, and body mass index are assessed. The DASH diet includes whole grains, fruits, vegetables, low-fat dairy products, fish, poultry, and legumes, and avoids creamy butter.

Category

Treatment - Other

2**Description**

Control group: In this group, no special diet is given and only low-fat, high-protein foods are recommended, which are evaluated by a doctor on a weekly basis for two months. Clinical outcomes such as preeclampsia, eclampsia, preterm delivery, placental abruption, Apgar scores in the first and fifth minutes, neonatal weight, and body mass index are assessed..

Category

Treatment - Other

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

Ahwaz Imam Khomeini Educational and Medical Center

Full name of responsible person

Mahin Najafian

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Azadegan St.

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drmahtab64@gmail.com

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

Ahwaz University of Medical Sciences

Full name of responsible person

Dr Mehdi Ahmadi Moghadam

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Ahwaz 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**

Ahwaz University of Medical Sciences

Full name of responsible person

Mahin Najafian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Ahwaz University of Medical Sciences

Full name of responsible person

Mahin Najafian

Position

Associate Professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data from this study can be shared after unidentified individuals.

When the data will become available and for how long

Start access from the time the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data of the present study can be used in any situation and anywhere

From where data/document is obtainable

Dr. Mahtab Shariati Email drmahtab64@gmail.com

Contact Number: 00989356515905

What processes are involved for a request to access data/document

Upon request of the applicant, the documents and the file that can be published will be emailed immediately after verification.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Mahtab Shariati

Position

Medical Student(Resident)

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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