

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect of Aspirin at doses of 80 and 160 mg on the prevention of preeclampsia in women with abnormal Doppler ultrasound of the uterine artery

Protocol summary

Study aim

Comparison of the effectiveness of aspirin with doses of 80 and 160 mg on the prevention of preeclampsia in women with abnormal Doppler ultrasound of the uterine artery

Design

This study includes two groups of intervention and control, which were divided into two groups of 150 people using a randomization table.

Settings and conduct

This study will be performed as a three-blind study in Sabzevar Medical Sciences Clinic in all women with impaired uterine artery Doppler. The patient and the assistant researcher and statistical analyst are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant mothers 18-22 weeks with abnormal uterine artery Doppler Exclusion criteria: Lack of cooperation and unwillingness of the mother to continue the plan, preterm delivery for reasons other than blood pressure

Intervention groups

Intervention group 1: Daily consumption of 80 mg of aspirin Intervention group 2: Daily consumption of 160 mg of aspirin

Main outcome variables

Preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210804052071N1**

Registration date: **2022-03-03, 1400/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-03, 1400/12/12**

Update count: **0**

Registration date

2022-03-03, 1400/12/12

Registrant information

Name

Mahboobeh Nikanjam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4423 8100

Email address

nikanjam_dr@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Aspirin at doses of 80 and 160 mg on the prevention of preeclampsia in women with abnormal Doppler ultrasound of the uterine artery

Public title

Comparison of the effect of Aspirin at doses of 80 and 160 mg on the prevention of preeclampsia in women with abnormal Doppler ultrasound of the uterine artery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant mothers at 18 to 22 weeks with impaired uterine artery Doppler Being single

Exclusion criteria:

Premature birth for reasons other than blood pressure
The mother's unwillingness to continue cooperating Not taking the right medication

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with the above conditions in two groups are randomly entered into one of the two intervention or control groups by blocking method (quadruple blocks). Thus, various quadrilateral blocks were created (AABB, BBAA, ABAB, BABA, ABBA and BABA). One of these blocks will be randomly selected and patients will be divided into one of two groups A or B.

Blinding (investigator's opinion)

Double blinded

Blinding description

The way of participant blindness is that she will receive and use a certain number of drugs in an unnamed and labeled envelopes. The investigators, participants, and evaluators will be blinded to assignment into the two groups (the groups taking the ASA+ ASA or taking the ASA+ placebo).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Sabzevar University of Medical Sciences

Street address

Mobini Hospital

City

Sabzevar

Province

Razavi Khorasan

Postal code

9313856776

Approval date

2021-12-29, 1400/10/08

Ethics committee reference number

IR.MEDSAB.REC.1400.128

Health conditions studied**1****Description of health condition studied**

Preeclampsia

ICD-10 code

O14

ICD-10 code description

Pre-eclampsia

Primary outcomes**1****Description**

Preeclampsia

Timepoint

During pregnancy up to 40 days after delivery

Method of measurement

Mercury sphygmomanometer, urine test

Secondary outcomes

empty

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

Intervention group: Pregnant women who will take aspirin 80 mg. Aspirin 80 mg from Galenus Pharmaceutical Company will be taken orally once a day from the time of enrollment until the end of pregnancy.

Category

Treatment - Drugs

2**Description**

Intervention group: Pregnant women who will take aspirin 160 mg. Aspirin 80 mg from Galenus Pharmaceutical Company will be taken orally 2 times a day from the time of enrollment until the end of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic of Sabzevar University of Medical Sciences

Full name of responsible person

Mitra Eftekhari Yazdi

Street address

Kashefi St, Mobini Hospital

City

Sabzevar

Province

Razavi Khorasan

Postal code

9313856776

Phone

+98 51 4423 8100

Email

m_eftekhari1144@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mitra Eftekhari Yazdi

Street address

Kashefi St, Mobini Hospital

City

Sabzevar

Province

Razavi Khorasan

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Phone

+98 51 4423 8100

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m_eftekhari1144@yahoo.com

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Mitra Eftekhari Yazdi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kashefi St, Mobini Hospital

City

Sabzevar

Province

Razavi Khorasan

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Phone

+98 51 4423 8100

Email

m_eftekhari1144@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mitra Eftekhari Yazdi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kashefi St., Mobini Hospital

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Sabzevar

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mitra Eftekhari Yazdi

Position

Associate professor

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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

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

A piece of data such as information about the main outcome or the possibility of sharing.

When the data will become available and for how long

Access period starts 6 months after 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

Necessary conditions for sending a request for access to the data or documents of the plan approval form in medical universities.

From where data/document is obtainable

The request for data will be sent via email and will be answered within a week after review.

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

The request for data will be sent via email and will be answered within a week after review.

Comments