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
atients 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 Haspital
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

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Sponsors / Funding sources

1

Sponsor

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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
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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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