

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Aspirin at a dose of 160 mg per day with the usual dose of Aspirin (80 mg daily) in the prevention of preeclampsia in high-risk pregnant women

Protocol summary

Study aim

The aim of this study was to compare the effect of aspirin at a dose of 160 mg per day with the usual dose of aspirin (80 mg daily) in preventing preeclampsia in high-risk pregnant women referred to Mahdiah Hospital.

Design

In this randomized clinical trial, 216 pregnant women at 12-20 weeks of gestation with high risk of preeclampsia are selected. Patients are randomly assigned to one of the two groups of aspirin at a dose of 80 mg daily or the aspirin group at a dose of 160 mg daily and are treated for 36 weeks, respectively, based on a random number table.

Settings and conduct

In this randomized clinical trial, 216 pregnant women at 12-20 weeks of gestation with high risk of preeclampsia are selected. For the first group, aspirin at a dose of 80 mg per day and for the second group, aspirin at a dose of 160 mg per day were considered. This research is performed in Mahdiah Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria encompass age over 18 years, presence of high-risk factors for preeclampsia (e.g., multiplet pregnancy, history of preeclampsia or inappropriate consequences in previous pregnancies. Patients with a history of heart, liver, thyroid, bleeding disorders, peptic ulcer, asthma, aspirin sensitivity, the presence of major fetal disorders and long-term use of NSAIDs are also excluded from the study.

Intervention groups

This study has 2 intervention groups. For the first group, aspirin at a dose of 80 mg per day and for the second group, aspirin at a dose of 160 mg per day were considered.

Main outcome variables

Preeclampsia; IUGR; Premature birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220410054469N1**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

Name

Paria Panahinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3333 9458

Email address

drpanahinia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Aspirin at a dose of 160 mg per day with the usual dose of Aspirin (80 mg daily) in the prevention of preeclampsia in high-risk pregnant women

Public title

The effect of Aspirin in preventing preeclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women at 12-20 weeks of gestation at high risk for Preeclampsia.

Exclusion criteria:

Patients who find it difficult to follow a regular pattern of medication. Patients with heart, liver, thyroid, peptic ulcer diseases and bleeding disorder. Patients with a history of asthma, aspirin sensitivity, and the presence of major fetal disorders.

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **216**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization of an individual using the rand function of EXCEL software. In this method, each person is assigned a number and based on software randomization, each person enters one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient and the researcher themselves were unaware of which control group (receiving the current routine drug, ie, 80 mg of aspirin daily) or intervention (receiving the dose of 80 mg of aspirin per day) belonged. For this purpose, patients in the control group are given two similar pills, one of which is a placebo.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran, Evin, Shahid Shahriari Square

City

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Province

Tehran

Postal code

1983969411

Approval date

2022-01-22, 1400/11/02

Ethics committee reference number

IR.SBMU.MSP.REC.1400.689

Health conditions studied

1

Description of health condition studied

Pre-eclampsia

ICD-10 code

O14

ICD-10 code description

Pre-eclampsia

Primary outcomes

1

Description

Incidence of Preeclampsia

Timepoint

From 12-20 to 36 weeks of pregnancy

Method of measurement

Mercury sphygmomanometer / laboratory abnormalities (including doubling of liver enzymes, doubling of serum creatinine and drop in platelets below 100,000)

Secondary outcomes

1

Description

Type of delivery (cesarean section or vaginal)

Timepoint

Time of delivery

Method of measurement

Based on medical file and disease progression

2

Description

Term or preterm delivery

Timepoint

Time of pregnancy termination

Method of measurement

Based on medical file and disease progression

Intervention groups

1

Description

Intervention group 1: Pregnant women in the 12-20 weeks of pregnancy who are at high risk of preeclampsia are treated with aspirin at a dose of 160 mg daily for 36 weeks. Aspirin tablets are provided by Sami Saz Company and are prescribed to patients. One 160 aspirin tablet is proscribed a day.

Category

Prevention

2

Description

Control group: Pregnant women who are prescribed aspirin 80 mg daily until the 36th week of pregnancy due to risk factors from 12-20 weeks of pregnancy. Aspirin 80 mg tablets are provided daily.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiyeh Educational Hospital

Full name of responsible person

Paria Panahinia

Street address

Mahdieh Hospital, Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq

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<https://www.sbmu.ac.ir/index.jsp?siteid=110>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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Web page address

<https://en.sbmu.ac.ir/index.jsp?siteid=256&fkeyid=&siteid=24&pageid=13079&siteid=256>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Paria Panahinia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

inclusion population and main outcome data

When the data will become available and for how long

Six months after the official release of the results

To whom data/document is available

Researchers, academics and industrial sectors

Under which criteria data/document could be used

The data will be used in meta-analysis research.

From where data/document is obtainable

Applicants can request the data by sending an email to Dr. Paria Panahinia. drpariapanahinia@yahoo.com

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

While introducing themselves and explaining the need for access, data will be sent to them within 10 days to 1 month.

Comments