Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of two various aspirin dosage (80mg and 120mg daily) on prevention of pre-eclampsia in high risk pregnant women

Protocol summary

Study aim
Comparison of the effect of two various doses of aspirin (80mg and 120mg daily) on preventing pre-eclampsia in high risk pregnant women referred to Mahdieh Hospital

Design
In this clinical trial, 729 pregnant women older than 18 years of age eligible for the study are randomly assigned into two groups of 80 mg or 120 mg daily oral aspirin, according to the random number table.

Settings and conduct
Pregnant women admitted to Mahdieh Hospital in Tehran, who are at high risk of pre-eclampsia and eligible for the study, are selected and randomly assigned to either 80mg or 120mg daily oral aspirin treatment group and treated up to 36 weeks. Participants will be visited monthly up to 28 weeks and every two weeks thereafter. In each visit, in addition to measuring blood pressure, the participants will be asked about the drug complications. All patients are carefully monitored for pregnancy outcomes such as pre-eclampsia, IUGR, and preterm delivery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women over 18 years of age, gestational age of 12-20 weeks, high risk factors for pre-eclampsia (such as multiple pregnancy, chronic hypertension, diabetes mellitus type 1 or 2, chronic kidney disease, autoimmune disease (antiphospholipid syndrome, lupus), history of pre-eclampsia or bad outcomes in previous pregnancies and the presence of a viable fetus Exclusion criteria: Cardiovascular, liver, thyroid, hemorrhagic or peptic ulcer disease, history of asthma, sensitivity to aspirin , major fetal disorders, and long-term use of NSAIDs

Intervention groups
Aspirin 80mg Group: Daily intake of oral aspirin (80mg) from entrance to the study up to delivery time Aspirin 120mg Group: Daily intake of oral aspirin (120mg) from entrance to the study up to delivery time Control group: Placebo

Main outcome variables
The incidence of pre-eclampsia

General information

Reason for update
number of groups and participants has changed

Acronym

IRCT registration information
IRCT registration number: **IRCT20120918010876N6**
Registration date: **2018-12-26, 1397/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-09, 1402/07/17**
Update count: **1**

Registration date
2018-12-26, 1397/10/05

Registrant information

Name
Masumeh Mirza Moradi

Name of organization / entity
Prinatalogy department of Mahdieh hospital

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two various aspirin dosage (80mg and 120mg daily) on prevention of pre-eclampsia in high risk pregnant women

Public title
Comparison of the effect of two doses of aspirin on the prevention of pre-eclampsia in high risk pregnant women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women over 18 years of age Gestational age of 12-20 weeks High risk factors for pre-eclampsia (such as multiple pregnancy, chronic hypertension, diabetes mellitus type 1 or 2 , chronic kidney disease, autoimmune disease (antiphospholipid syndrome, lupus) History of pre-eclampsia or bad outcomes in previous pregnancies The presence of a viable fetus
Exclusion criteria:
Existence of Cardiovascular, liver, thyroid, hemorrhagic or peptic ulcer diseases History of asthma Sensitivity to aspirin Major fetal disorders Prolonged use of NSAIDs
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **729**
Randomization (investigator's opinion)
Randomized
Randomization description
A 22-by-22 table, which is randomly generated by the computer and contains numbers from 1 to 729, is used. Selecting a sample starts at the first cell from top and left of the table and goes left to right and up to down. Odds numbers are assigned to the aspirin 80mg group and even numbers are assigned to the aspirin 120mg group.
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
Ethic's committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak St., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2018-10-23, 1397/08/01
Ethics committee reference number
IR.SBMU.MSP.REC.1397.531

Health conditions studied

1

Description of health condition studied
Preeclampsia
ICD-10 code
O14
ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
The incidence of pre-eclampsia
Timepoint
Monthly up to 28 weeks of pregnancy, then every two weeks up to 36 weeks of pregnancy and eventually every week until the delivery time
Method of measurement
Blood pressure measurement and clinical examination

Secondary outcomes

1

Description
Gastrointestinal complications of aspirin (heartburn, gastrointestinal bleeding)
Timepoint
Monthly up to 28 weeks of pregnancy, then every two weeks up to 36 weeks of pregnancy and eventually every week until the delivery time
Method of measurement
Question from patient and clinical examination

2

Description
The incidence of intra-uterine growth retardation (IUGR)
Timepoint
Monthly up to 28 weeks of pregnancy, then every two weeks up to 36 weeks of pregnancy and eventually every week until the delivery time
Method of measurement
Clinical examination

3

Description
The incidence of preterm delivery
Timepoint
Monthly up to 28 weeks of pregnancy, then every two weeks up to 36 weeks of pregnancy and eventually every week until the delivery time
Method of measurement
Gestational age at delivery

4

Description
Vaginal bleeding as side effect of aspirin
Timepoint
Monthly up to 28 weeks of pregnancy, then every two weeks up to 36 weeks of pregnancy and eventually every week until the delivery time
Method of measurement
Question from patient and clinical examination

Intervention groups

1

Description
Intervention group: Daily oral aspirin (80mg)
Category
Treatment - Drugs

2

Description
Intervention group: Daily oral aspirin (120mg)
Category
Treatment - Drugs

3

Description
Control group: Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Dr. Masoome Mirzamoradi
Street address
Mahdieh Hospital, Shoosh Sq.
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1185817311
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ali Ziayee
Street address
Next to Taleghani Hospital, Shahid Arabi St., Yemen St., Chamran Highway
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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
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

Masoome Mirzamoradi

Position
Perinatologist

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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mahdie hospital- shoosh sq- -tehran

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Contact

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Position
Perinatologist

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No need for publication

Study Protocol
No - There is not 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
Undecided - It is not yet known if there will be 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