

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 Mahdiah 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 Mahdiah 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

Prinatology department of Mahdiah hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 6263

Email address

m-bakhtiyari@razi.tums.ac.ir

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

Mahdiah Hospital

Full name of responsible person

Dr. Masoome Mirzamoradi

Street address

Mahdiah Hospital, Shoosh Sq.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

mahdiah-hospital@yahoo.com

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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Phone

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Mpajouhesh@sbmu.ac.ir

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

Masoom 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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Masoom Mirzamoradi

Position

Perinatologist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Dr. Masoom Mirzamoradi

Position

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Latest degree

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Other areas of specialty/work

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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