

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of Aspirin dose (80 and 160 mg) in prevention of preeclampsia and maternal fetal complications

Protocol summary

Study aim

Comparison of Aspirin dose (80 and 160 mg) in prevention of preeclampsia and maternal fetal complications

Design

A controlled clinical trial, with parallel groups, randomized

Settings and conduct

This randomized clinical trial will be conducted in Shahid Akbarabadi Medical Center in 1398. Simple sampling will be done from pregnant women with gestational age of 12 to 16 weeks who referred to the hospital's prenatal clinic would be selected based on inclusion criteria. Samples will be randomly assigned to two groups (each group of 40): the group receiving aspirin 80 mg and the group receiving aspirin 160 mg. Demographic characteristics including age, body mass index, pregnancy number, systolic and diastolic blood pressure were recorded at the first visit. Pregnant mothers will be visited every two weeks until gestational age of 28 weeks and after that will be visited weekly until the termination of pregnancy.

Participants/Inclusion and exclusion criteria

Pregnant women at 12 to 16 weeks of gestation referring to the prenatal clinic of Shahid Akbarabadi Hospital have at least one of the following conditions: Previous history of preeclampsia, chronic hypertension, type 1 and type 2 diabetes, kidney disease, autoimmune disease, Or have at least two of the following conditions: nulliparity, obesity, over 35 years old, low socioeconomic status, Pregnancy interval over 10 years, history of stillbirth

Intervention groups

Intervention group I: Pregnant women receiving 80 mg aspirin. Intervention group II: Pregnant women receiving 160 mg aspirin.

Main outcome variables

preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190826044619N1**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **retrospective**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Maryam Chamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8856 2080

Email address

chamani.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Aspirin dose (80 and 160 mg) in prevention of preeclampsia and maternal fetal complications

Public title

Comparison of Aspirin dose in prevention of preeclampsia and maternal fetal complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The pregnant mother has completed the consent form to participate in the study. Pregnant mother is 12 to 16 weeks pregnant. The pregnant mother has at least one of the following criteria: a history of previous preeclampsia, polygamy, chronic hypertension, type 1 and type 2 diabetes, kidney disease, autoimmune disease (such as lupus). Or the pregnant mother has at least two of the following criteria: nulliparity, obesity, age over 35, low level of socioeconomic status, gap between pregnancies over 10 years, adverse pregnancy outcome (stillbirth, etc.)

Exclusion criteria:

The pregnant mother has peptic ulcer. The pregnant mother has gout.

Age

No age limit

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be divided into study groups based on random allocation rule (each group of 40) . Forty sample will be selected randomly by lottery method from the entire sample, and assigned to the 80 mg aspirin group and the remaining sample assigned to the 160 mg aspirin 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

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-03-04, 1397/12/13

Ethics committee reference number

IR.IUMS.FMD.REC.1398.133

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

Each 2 week from 20 to 28 weeks of gestational age and after that weekly until the termination of pregnancy.

Method of measurement

Systolic blood pressure greater than 1 mmHg or diastolic blood pressure greater than 1 mmHg

Secondary outcomes

1

Description

Preterm delivery

Timepoint

Mother's delivery

Method of measurement

Maternal gestational age is less than 37 weeks.

2

Description

Method of childbirth

Timepoint

Mother's delivery

Method of measurement

Cesarean section or Vaginal delivery

3

Description

Intrauterine fetal growth restriction

Timepoint

Every two weeks from the start of the intervention until the 28th week of pregnancy

Method of measurement

sonography

4

Description

Apgar score minute1

Timepoint

1 minute after birth

Method of measurement

Grading to Appearance, Pulse, Grimace, Activity and Respiration of baby

5

Description

Apgar score minute 5

Timepoint

5 minutes after birth

Method of measurement

Grading to Appearance, Pulse, Grimace, Activity and Respiration of baby

Intervention groups

1

Description

Intervention group: Pregnant women who will take aspirin 160 mg.The 80 mg Aspirin by the Jalinus Pharmaceutical Company will be used orally 2 times a day from the time of study until the end of the 36th week of pregnancy.

Category

Treatment - Drugs

2

Description

control group: Pregnant women who will take aspirin 80 mg.The 80 mg Aspirin by the Jalinus Pharmaceutical Company will be used orally once a day from the time of study until the end of the 36th week of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Perinatal clinic of Shahid Akbarabadi hospital

Full name of responsible person

Maryam Chamani

Street address

Bagh Ferdows Station., Mowlavi St

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akbarabadihosp@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Chamani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address1st Floor, Unit 6, Pearl Complex, North Motahhari St,
Darya Boulevard, Saadat Abad Ave.**City**

Tehran

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available