

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of 80 and 150 mg aspirin on maternal and fetal factors in first trimester of pregnancy in women who is high risk for preeclampsia in patients referred to teaching hospitals of Shiraz University of Medical Sciences

Protocol summary

Study aim

Comparison of the effect of 80 and 150 mg aspirin on maternal and fetal factors in first trimester of pregnancy in women who is high risk for preeclampsia in patients referred to teaching hospitals of Shiraz University of Medical Sciences

Design

In our research, we will select 100 high risk pregnant women for preterm labor based on first trimester doppler sonography, then with block randomizing method we will place them on two groups. 50 patient will receive 80 mg aspirin and other group will receive 100 mg aspirin. Treatment starts since 11-13 week of pregnancy until 34 week or delivery time.

Settings and conduct

Between all pregnant women who will come to educational hospital in Shiraz city until 21/3/2021, 100 person who are high risk for preterm labor based on first trimester doppler ultrasonography will be selected and they will be assigned in two groups with bloc randomizing method. 50 patients will receive 80 mg aspirin and the other will receive 100 mg aspirin. Finally the results between two groups will be compared .it needs to be mentioned that all tablets will be used in two groups have the same shape ,color and size. . The nurse of research center has the list of randomized and grouping and tablets, and she will give drugs to the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: singleton pregnant women who are at high risk for uteroplacental ischemia and preterm labor according to increased uterine artery resistant in first trimester doppler ultrasonography. Exclusion criteria: multiple pregnancy; fetal aneuploidy; fetal anomaly; coagulation disorder; allergy to aspirin; women who use aspirin or heparin before starting study.

Intervention groups

50 person will receive 80 mg aspirin and the other 50 person will receive 150 mg aspirin.

Main outcome variables

Decrease fetal mortality and morbidity due to severe preeclampsia & GDM

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140317017035N7**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **prospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

Registration date

2020-11-28, 1399/09/08

Registrant information

Name

Maryam Kasraeian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 32365

Email address

kasraeem@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-10, 1399/09/20

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 80 and 150 mg aspirin on maternal and fetal factors in first trimester of pregnancy in women who is high risk for preeclampsia in patients referred to teaching hospitals of Shiraz University of Medical Sciences

Public title

Effect of Aspirin on on maternal and fetal factors

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The singleton pregnant women who are high risk for uteroplacental preeclampsia and GDM based on increased uterine artery resistant on first trimester doppler ultrasonography.

Exclusion criteria:

Multiple pregnancy Fetal aneuploidy Fetal anomaly Coagulation disorder Allergy to aspirin Women who use aspirin or heparin before starting study

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In our research, we will select 100 high risk pregnant women for preterm severe preeclampsia & GDM based on first trimester doppler sonography, then with block randomizing method with 4th and 6th block, we will place them on two groups. 50 patient will receive 80 mg aspirin and other group will receive 150 mg aspirin. Treatment starts since 11-13 week of pregnancy until 34 week or delivery time(each one occur sooner.)

Blinding (investigator's opinion)

Double blinded

Blinding description

All tablet use in two groups are the same shape, color and size. Patients and doctors are unaware about dosages that is chosen in each person. The nurse of

research center has the list of randomized and grouping and tablets and she will give drugs to the patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Province

Fars

Postal code

Headquarters Of Shir

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.SUMS.MED.REC.1398.642

Health conditions studied**1****Description of health condition studied**

Severe preeclampsia

ICD-10 code

JA24

ICD-10 code description

Pre-eclampsia

Primary outcomes**1****Description**

Decrease fetal mortality and morbidity due to preeclampsia

Timepoint

After birth

Method of measurement

Vital Signs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 50 person will receive 80 mg aspirin until 34 weeks

Category

Treatment - Drugs

2

Description

Intervention group: 50 person will receive 150 mg aspirin until 34 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital of Shiraz University of Medical Sciences

Full name of responsible person

Syedeh Fateme Khaleghi

Street address

Hafez Hospital; Shahid Chamran blvd

City

Shiraz

Province

Fars

Postal code

34786-71946

Phone

+98 71 3612 8257

Email

alifatijoon1396@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Yoones Ghasemi

Street address

Building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

Province

Fars

Postal code

34786-71946

Phone

+98 71 3235 7282

Email

ghasemiy@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sydeh Fateme Khaleghi

Position

Resident of obstetrics and gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

34786-71946

Phone

+98 71 3233 2365

Email

alifatijoon1396@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Kasraeian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

34786-71946

Phone

+98 71 3612 8258

Email

maryamkasraeian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Kasreian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

34786-71946

Phone

+98 71 3612 8257

Email

maryamkasraeian@gmail.com

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

Not applicable

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

IPD: Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long

IPD: 2020 Ethic form: 2020

To whom data/document is available

IPD: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used

IPD: Ethic form: Awareness of test results

From where data/document is obtainable

IPD: OB & Gyn ward Shiraz university of medical sciences
Ethic form: OB & Gyn ward Shiraz university of medical sciences

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

IPD: Vice chancellery Ethic form: Vice chancellery

Comments