

# 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**

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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**