

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of aspirin on the incidence of preeclampsia and fetal growth restriction in obese pregnant women

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Evaluation of the effect of aspirin administration on prevention of preeclampsia and fetal growth restriction in obese pregnant women

Last update: **2019-10-02, 1398/07/10**

Update count: **0**

#### Registration date

2019-10-02, 1398/07/10

#### Design

This study is a randomized clinical trial that will be performed on 187 obese pregnant women referred to Yasuj Shahid Mofteh Clinic affiliated with Yasuj University of Medical Sciences in 2018-2019.

#### Registrant information

##### Name

Fatemeh Bazarganipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3366 6367

##### Email address

bazarganipour@hums.ac.ir

#### Settings and conduct

Intervention group: Aspirin, one dose of aspirin 1 mg daily until 34 weeks of pregnancy was used. Control group: placebo was used one day until 34 weeks of pregnancy.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-40 Single pregnancy Tends to participate in the study Non underlying known disease such as chronic hypertension, liver disease, kidney disease, diabetes mellitus No using aspirin or allergy history BMI $\geq$ 30 No ultrasound findings On NT, mean PI Ut>1.5 or PAPP A <0.4 No history of previous preeclampsia No history of previous fetal growth restriction Normality of tests and screening Exclusion criteria: Unwillingness to participate in study Not available for evaluations Abortion and preterm delivery for reasons other than preeclampsia and fetal growth restriction

#### Expected recruitment start date

2019-04-21, 1398/02/01

#### Expected recruitment end date

2020-04-20, 1399/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

Aspirin compared to placebo

#### Main outcome variables

Preeclampsia, fetal growth restriction

#### Scientific title

The effect of aspirin on the incidence of preeclampsia and fetal growth restriction in obese pregnant women

#### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160524028038N5**

Registration date: **2019-10-02, 1398/07/10**

#### Public title

Aspirin and preeclampsia and fetal growth restriction in obese pregnant Women

#### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 18-40 Single pregnancy Tends to participate in the study Non underlying known disease such as chronic hypertension, liver disease, kidney disease, diabetes mellitus No using aspirin or allergy history BMI $\geq$ 30 No ultrasound findings On NT, mean PI Ut>1.5 or PAPPA <0.4 No history of previous preeclampsia No history of previous fetal growth restriction Normality of tests and screening

### Exclusion criteria:

Unwillingness to participate in study Not available for evaluations Abortion and preterm delivery for reasons other than preeclampsia and fetal growth restriction

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **194**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization method is simple. The sealed envelopes encoded and non-transparent (A and B) for the allocation of subjects to intervention (A) and control (B) groups will be used.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Used

### Assignment

Parallel

## Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

##### Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad

##### City

yasuj

##### Postal code

7916839319

#### Approval date

2019-02-16, 1397/11/27

## Ethics committee reference number

IR.YUMS.REC.1397.152

## Health conditions studied

### 1

#### Description of health condition studied

Preeclampsia

#### ICD-10 code

O14.0

#### ICD-10 code description

Mild to moderate pre-eclampsia

### 2

#### Description of health condition studied

Fetal growth restriction

#### ICD-10 code

P05.1

#### ICD-10 code description

Newborn small for gestational age

## Primary outcomes

### 1

#### Description

Preeclampsia

#### Timepoint

End of pregnancy

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

Fetal growth retardation

#### Timepoint

End of pregnancy

#### Method of measurement

Sonography

## Intervention groups

### 1

#### Description

Intervention group: Take one dose of aspirin 80 mg daily until 34 weeks of gestation

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Take one dose of placebo daily until 34 weeks of gestation

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yasuj University of Medical Sciences

**Full name of responsible person**

Maryam Sadeghian

**Street address**No. 7916839319, Shahid Jalil Ave., Yasuj Town,  
Kohgiluyeh and Boyer-Ahmad**City**

Kohgiluyeh and Boyer-Ahmad

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7916839319

**Phone**

+98 74 3333 7251

**Email**

dr.sadeghian64@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Hossein Mari-Oriadi

**Street address**No. 7916839319, Shahid Jalil Ave., Yasuj Town,  
Kohgiluyeh and Boyer-Ahmad**City**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Maryam Sadeghian

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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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 more information

**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**

No - There is not 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