

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Using of low dose aspirin in the prevention of preeclampsia in pregnant women with abnormal uterin Doppler at 11-14 weeks gestation

#### Protocol summary

##### Summary

The aim of our study is to determine the effectiveness of aspirin in redusing the prevention of preeclampsia in pregnant women with abnormal findings at uterine artery Doppler velocimetry perfume at 11-14 weeks.The design is randomized controlled clinical trial.All participants will attended the antenatal clinic in Emam hospital of Sari during the period from 1392-1393 years.In addition to the routine ultrasound will done in all participants to evaluate the pregnancy at the time of booking.All patients have Doppler velocimetry of the uterin artery either by transabdominal or transvaginal route.The outcome measures will the resistance index and palsatility index of the uterine artery.Patients show to have normal Doppler findings will excluded,wheras those with abnormal results(the presence of unilateral or bilateral uterin artery resistance index higher than 90th percentile for age)will explaired the whole procedure.The number of 100 patients agree to sign consent and they will randomly dividing in two groups.Group1(50 patients)will treated with acetylsalicylic oral tablets and the control group(50 patients)will not give any treatment.All women will followup until delivery to assess maternal perinatal outcoms.They will also monitor for blood pressure and proteinuria on regular basis.The primery outcome criteria will the development preeclampsia,time of onset,criteria of severity.The second outcome criteria will intrauterine growth restriction,preterm delivery,still birth and maternal bleeding that need to transfusion.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013072914198N1**

Registration date: **2013-09-14, 1392/06/23**

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

Last update:

Update count: **0**

##### Registration date

2013-09-14, 1392/06/23

##### Registrant information

###### Name

Zoleikha Atarod

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1226 1700

###### Email address

zatarod@mazums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mazandaran University of Medical Sciences

##### Expected recruitment start date

2013-06-01, 1392/03/11

##### Expected recruitment end date

2014-10-01, 1393/07/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Using of low dose aspirin in the prevention of preeclampsia in pregnant women with abnormal uterin Doppler at 11-14 weeks gestation

##### Public title

Using of aspirin in the prevention of preeclampsia

##### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancies at 11-14 weeks and with risk factors for preeclampsia such as; nulliparous women. Exclusion criteria; Fetal chromosomal or structural abnormalities, allergy to acetylsalicylic tablets, medical conditions: renal, lupus and coronary artery heart disease, bleeding disorders.

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 100

## Randomization (investigator's opinion)

N/A

## Randomization description

## 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

Mazandaran University of Medical Sciences

##### Street address

Emam hospital, Sari

##### City

Sari

##### Postal code

#### Approval date

2013-02-27, 1391/12/09

#### Ethics committee reference number

1517

### 2

#### Ethics committee

##### Name of ethics committee

Mazandaran university of medical sciences

##### Street address

Emam hospital

##### City

sari

##### Postal code

#### Approval date

2013-02-27, 1391/12/09

## Ethics committee reference number

1517

## Health conditions studied

### 1

#### Description of health condition studied

Preeclampsia

#### ICD-10 code

O14

#### ICD-10 code description

Gestational [pregnancy-induced] hypertension with significant proteinuria

### 2

#### Description of health condition studied

preeclampsia

#### ICD-10 code

O14.0, O14.

#### ICD-10 code description

پره اکلامپسی خفیف-پره اکلامپسی شدید-پره اکلامپسی با علایم غیر اختصاصی

## Primary outcomes

### 1

#### Description

Diagnosis of preeclampsia

#### Timepoint

2 month after onset-every 4 week-End of treatment

#### Method of measurement

Monitor of blood pressure and proteinuria

### 2

#### Description

Time of onset of preeclampsia

#### Timepoint

2 month after onset-every 4 week-End of treatment

#### Method of measurement

LMP and ultrasound at time of booking

### 3

#### Description

Criteria of severity of preeclampsia

#### Timepoint

2 month after onset-every 4 week-End of treatment

#### Method of measurement

Monitor for blood pressure and proteinuria and symptoms and signs

## Secondary outcomes

### 1

#### Description

Maternal bleeding that need to transfusion

#### Timepoint

From delivery for 24 hours after  
**Method of measurement**  
Signe and symptoms-decreasing of Hb after delivery-nu

## 2

### **Description**

Intrauterine growth restriction

### **Timepoint**

ماه بعد از شروع مطالعه-هر 4 هفته-پایان مطالعه

### **Method of measurement**

When the fetal weight will below the 10th percentile for gestational in ultrasound and also when the neonatal birth weight will fill bellow the 10th percentile

## 3

### **Description**

Preterm delivery

### **Timepoint**

2 month after onset-every 4 week-End of treatment

### **Method of measurement**

LMP and ultrasound at time of booking

## 4

### **Description**

Still birth

### **Timepoint**

2 month after onset-every 4 week-End of treatment

### **Method of measurement**

With FHR monitoring and ultrasound

## **Intervention groups**

## 1

### **Description**

Intrvention description:Tab ASA 80 mg daily after lunch

### **Category**

Treatment - Drugs

## 2

### **Description**

Controlled trial:No treatment

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

**Name of recruitment center**

Emam Khomeini hospital

**Full name of responsible person**

**Street address**

**City**

Sari

## **Sponsors / Funding sources**

## 1

### **Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr.Mohamadreza Shiran

**Street address**

Juibar forked road, Emam square, Sari

**City**

Sari

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mazandaran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

## **Person responsible for general inquiries**

### **Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr.Zoleikha Atarod

**Position**

Obstetrician

**Other areas of specialty/work**

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## **Person responsible for scientific inquiries**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*