

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of low dose Aspirin on endothelial dysfunction in preeclamptic patients

Protocol summary

Summary

The aim of this study is to evaluate the effect of Aspirin on endothelial dysfunction in preeclamptic patients. Pregnancy and suffering from preeclampsia are inclusion criteria and patients with major underlying disease and who consumed drug incompletely, will be excluded from the study. Eighty five patients are divided randomly into two groups. Aspirin 80 mg or placebo will be taken daily by oral administration from the initiation of diagnosis until 2 months after delivery by the trial participant. Every patient's Flow Mediated Dilation will be evaluated at the beginning of study and 2 months after delivery with the same experienced operator at a same period of the time (3-5 p.m.) by High resolution B-mode ultrasonographic.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040527135N2**

Registration date: **2016-06-04, 1395/03/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-04, 1395/03/15

Registrant information

Name

Saeide Bahrani

Name of organization / entity

Isfahn University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 435 0474

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isrc_info@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of low dose Aspirin on endothelial dysfunction in preeclamptic patients

Public title

Effect of aspirin on prevention of preeclampsia consequences

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnancy; preeclampsia Exclusion criteria: Major underlying diseases; incomplete drug consumption

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **85**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee
Isfahn University of Medical Sciences
Street address
Isfahn University of Medical Sciences, Hezar jarib st,
Isfahan
City
Isfahan
Postal code
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
ir.mui.rec.1394.3.649

Health conditions studied

1
Description of health condition studied
Pre-eclampsia
ICD-10 code
O14.9
ICD-10 code description
Pre-eclampsia, unspecified

Primary outcomes

1
Description
flow mediated dilation of brachial artery
Timepoint
before and after intervention
Method of measurement
High resolution B-mode ultrasonographic

Secondary outcomes

1
Description
lipid profile
Timepoint
before and after intervention
Method of measurement
laboratory test

Intervention groups

1
Description
asprin, tablet, 80 mg, oral, from the initiation of
diagnosis until 2 months after delivery
Category
Treatment - Drugs

2
Description
placebo, tablet, 80 mg, oral, daily, from the initiation of
diagnosis until 2 months after delivery
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
St-zahra Educational Hospital
Full name of responsible person
Forouz Baktash
Street address
Isfahan University of Medical Sciences, Hezar jarib St,
Isfahan, Iran
City
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mrs Eshghi
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City
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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

Isfahan 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
Isfahn University of Medical Sciences
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Forouz Baktash
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Person responsible for scientific inquiries

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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