Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of High dose Folic acid on endothelial dysfunction in preeclamptic patients

Protocol summary

Summary
Aim of this study is to evaluate the effect of High dose Folic acid 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 two patients are divided randomly into two groups. Folic acid 5.0 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: **IRCT2016032727135N1**
Registration date: **2016-04-24, 1395/02/05**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2016-04-24, 1395/02/05

Registrant information
Name
Saeide Bahrani
Name of organization / entity
Isfahn University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Isfahn University of Medical Sciences

Expected recruitment start date
2015-06-21, 1394/03/31
Expected recruitment end date
2016-04-20, 1395/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of High dose Folic acid on endothelial dysfunction in preeclamptic patients

Public title
Effect of folic acid on prevention of preeclamsia 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: **82**

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
Isfahan University of Medical Sciences

Street address
isfahan 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.1394.3.653

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
folic acid, tablet, 50 mg, once daily, from the begining of the intervention until 2 months after delivery

Category
Treatment - Drugs

2

Description
placebo, tablet, PO, from the begining of the intervention 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
Kian Heshmat

Street address
Isfahn University of Medical Sciences, Hezar jarib St, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahn University of Medical Sciences

Full name of responsible person
Mrs Eshghi

Street address
Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

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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

Isfahn 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

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Cardiology resident

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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