

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

Country

Iran (Islamic Republic of)

Phone

+98 913 435 0474

Email address

isrc_info@med.mui.ac.ir

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 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: **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 beginning of the intervention until 2 months after delivery

Category

Treatment - Drugs

2

Description

placebo, tablet, PO, from the beginning 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,
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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

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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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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