

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of high dose and low dose folic acid supplementation on prevalence, onset and severity of preeclampsia

Protocol summary

Summary

In this double-blinded randomized clinical trial study we would like to compare the effect of high dose (5 mg daily) and low dose (1 mg daily) of folic acid supplementation on prevalence, onset and severity of preeclampsia. nine-hundred pregnant women who are in first trimester with sigelton or twin pregnancy and referred to Shahidbeheshti and Alzahra university hospitals of Isfahan-Iran for two years (10/10/91 and 9/10/93) that not conterasndication of folic acid with satisfaction will include in to the study and if fetal death during the study, major abnormality of the fetus, women who were planning to move outside of the catchment area of the study within the pregnancy duration left study. They are divided randomized computer into two groups of 5mg (treated with daily 5 mg of folic acid) and 1mg (treated with daily 1 mg of folic acid).The first assessment of women was done about complete medical and obstetrical history, physical exam, demographic data (age, weigh, height, BMI and gravidity), calculating gestational age, vital sign (specially systolic and diastolic blood pressure and laboratory data including urine analysis, platelet count, liver function tests (including AST and ALT) and serum's creatinine and making prenatal card. and platelet count will evaluated in a 9-months clinical follow up . The study participants were pregnant women who have received prenatal cares at the study clinics since first visit to delivery for sign of preeclampsia and followed up at least 42 days after child birth in this clinics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507313944N4**

Registration date: **2015-10-21, 1394/07/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-21, 1394/07/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-12-30, 1391/10/10

Expected recruitment end date

2014-12-30, 1393/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of high dose and low dose folic acid supplementation on prevalence, onset and severity of preeclampsia

Public title

High dose folic acid supplementation effect on preeclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all of women with living fetus in the uterine cavity in first trimester with willingness for participation in this study, were included and do not: Presence or history of a disorder in which administration of folic acid is contraindicated, renal diseases, using anti-epileptic drugs (since the metabolism of anti-epileptic drugs requires a great deal of folic acid), malignancy, alcohol abuse, multiple birth (presence of three living fetus or more) and known hypersensitivity to folic acid (rashes, dermatologic and gastroenterological discomforts). Exclusion criteria: Fetal death during the study, major abnormality of the fetus, women who were planning to move outside of the catchment area of the study within the pregnancy duration.

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **900**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences committee

Street address

Shahidbeheshti Hospital ,Polfelezi

City

Isfahan

Postal code

8184851153

Approval date

2012-12-30, 1391/10/10

Ethics committee reference number

393587

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O14.9

ICD-10 code description

Gestational [pregnancy-induced] hypertension with significant proteinuria

Primary outcomes

1

Description

preeclampsia

Timepoint

first visit and routine prenatal care

Method of measurement

measurement blood pressure (mmHg) and proteinuria(mg/dl)

Secondary outcomes

1

Description

incidence of preeclampsia

Timepoint

during pregnancy

Method of measurement

using diagnostic criteria

2

Description

severity of preeclampsia

Timepoint

during pregnancy

Method of measurement

using diagnostic criteria

3

Description

prevalence of preeclampsia

Timepoint

during pregnancy

Method of measurement

using diagnostic criteria

Intervention groups

1

Description

Case group will administered 5 milligrams of folic acid daily from first trimester of pregnancy until termination

Category

Treatment - Drugs

2

Description

case group will receive 1 milligram of folic acid daily from first trimester of pregnancy until termination

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti Hospital and Alzahra Hospital

Full name of responsible person

Dr Azar Danesh

Street address

Shahidbeheshti Hospital Polfelezi

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Azar Danesh Shahraki

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Shahidbeheshti Hospital,Polfelezi

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Isfahan

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

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Full name of responsible person

Dr Azar Danesh

Position

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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