Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of prenatal administration of high dose and low dose folic acid on maternal plasma homocysteine concentration and its relationship with preeclampsia

Protocol summary

Summary

OBJECTIVE: To evaluate effects of high and low dose folic acid on levels of hemocysteine (Hcy) concentration during first trimester of pregnancy and at delivery, and to examine the association of Hcy serum levels and preeclampsia. METHODS: A single blinded randomized clinical trial was conducted in Tabriz, Iran, from 2006-2013, in 400 nulliparous pregnant women in 2 groups, who received folic acid daily from early pregnancy until delivery (5 mg/day and 0.5 mg/ day respectively). The incidence of pregnancy induced hypertension, preeclampsia, eclampsia and laboratory changes in the levels of serum Hcy, Platelet numbers, lactate dehydrogenase, uric acid, serum and urine creatinine and serum and urine protein were compared. Maternal blood pressure and weight were checked in each visit including labor time. The number of abortions, premature labor, IUGR, fetal death, PIH, preeclampsia, eclampsia , birth weight, congenital abnormalities, date of pregnancy termination, and meconium staining were reported in a questionnaire. Healthy mothers with a singleton pregnancy aged between 20-30 years old were included and patients with heart disease; chronic hypertension; diabetes mellitus; collagen vascular diseases; chronic renal disease; and who taking medications other than calcium and ferrous sulfate and vitamin B6 were excluded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402175283N9**
Registration date: **2014-03-25, 1393/01/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-03-25, 1393/01/05

Registrant information

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Manizheh Sayyah Melli
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

vise chancellor for research of tabriz university of medical sciences

Expected recruitment start date

2006-08-22, 1385/05/31

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of prenatal administration of high dose and low dose folic acid on maternal plasma homocysteine concentration and its relationship with preeclampsia

Public title

The effect of prenatal administration of folic acid on

maternal plasma homocysteine concentration and its relationship with the development of preeclampsia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Healthy mothers with a singleton pregnancy aged between 20-30 years old Exclusion criteria: Heart disease; chronic hypertension; Diabetes mellitus; collagen vascular diseases; chronic renal disease; preterm delivery for the other reasons except preeclampsia; taking medications other than calcium and ferrous sulfate and vitamin B6.

Age
From **20 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **400**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Golgasht Ave, Tabriz, Iran

City
Tabriz

Postal code

Approval date
2006-12-30, 1385/10/09

Ethics committee reference number
5/4/8281

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
Decreasion in homocysteine level

Timepoint
first trimester and at delivery time

Method of measurement
serum sampeling

2

Description
prevention of preeclampsia

Timepoint
after 20th week of pregnancy age

Method of measurement
controling of severe signs, body weight, blood pressure, edema, urine protein in every visit

Secondary outcomes

1

Description
preterm labor

Timepoint
labor after 20-37

Method of measurement
clinical examination

2

Description
Prevention of IUGR

Timepoint
After 24 weeks every month

Method of measurement
sonography

Intervention groups

1

Description
Control group: folic acid 0.5mg/day from the beginning of the pregnancy to the end.

Category
Treatment - Drugs

2

Description
Intervention group: folic acid 5mg/day from the beginning of the pregnancy to the end.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Manizheh Sayyah melli
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences and Health Services
Full name of responsible person
Dr Hossein Babayi
Street address
Daneshgah Ave, Tabriz, Iran
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Drug Applied Research Center, Tabriz University of Medical Sciences and Health Services
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
Tabriz University of Medical Sciences
Full name of responsible person
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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