

# 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 homocysteine (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

###### Name

Manizheh Sayyah Melli

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

###### Recruitment complete

##### Funding source

vice 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**

controlling 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**

Manizheh Sayyah-Melli

**Position**

Full Professor

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**Web page address****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*