

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of prenatal administration of folic acid on serum homocysteine and lipoprotein (a) levels in Methylenetetrahydrofolate reductase polymorphisms

Protocol summary

Summary

Objective: - Assumptions: 1 - Administration of folic acid reduces serum Hcy levels in Pregnant women 2 - Administration of folic acid reduces serum Lp(a) levels in Pregnant women 3 - Effect of administration of folic acid in reducing Hcy and Lp(a) serum dependent on type of genotype in Methylenetetrahydrofolate reductase polymorphisms -Objectives : a) The general purpose design: Determining effect of administration folic acid in pregnancy on serum homocysteine and LP(a) in Methylenetetrahydrofolate reductase polymorphisms (MTHFR 677C → T) b) The specific objectives of the project : 1 - Determining effect of administration folic acid on Hcy serum in pregnant women 2 - Determining effect of administration folic acid on Lp (a) serum in pregnant women 3 - Determining effect of administration folic acid in pregnancy on serum homocysteine and LP(a) of pregnant women in different genotypes of Methylenetetrahydrofolate reductase b) practical objectives: To clarify the requirement rate of folic acid in pregnant women according to their genotype types to reduce Hcy and Lp (a) serum with purpose of reducing the risk of Pre-eclampsia pregnancy planning of study: Interventional-clinical trial The study population: Pregnant women the main criteria for inclusion: Pregnant women, average age of 20 -30 years the main criteria for Exclusion: History of heart disease, chronic hypertension, diabetes mellitus, renal disease, collagen tissue disease, history of preterm labor, abortion, taking calcium and ferrous sulfate, liver disease sample size: 90 patients studied intervention or interventions: Administration 5 mg of folic acid Date of intervention: blood sampling from pregnant women before Administration and 36 weeks of gestation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010715903N2**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Nadereh Rashtchizadeh

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

Drug Applied Research Center

Expected recruitment start date

2014-03-01, 1392/12/10

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prenatal administration of folic acid on serum homocysteine and lipoprotein (a) levels in Methylenetetrahydrofolate reductase polymorphisms

Public title

Effect of prenatal administration of folic acid on serum homocysteine and lipoprotein (a) levels in Methylenetetrahydrofolate reductase polymorphisms

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with the average age of 20-30 years Exclusion criteria: Without history of heart disease; chronic hypertension; diabetes mellitus; renal disease; collagen tissue disease; history of preterm labor; abortion; drug taking calcium and ferrous sulfate; liver disease

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: **90**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Drug Applied Research Center

Street address

Department of Biochemistry and Clinical Laboratory,
Faculty of Medical science, Tabriz University of
Medical science

City

Tabriz

Postal code

Approval date

2013-12-02, 1392/09/11

Ethics committee reference number

7576/4/5

Health conditions studied

1

Description of health condition studied

Pregnant Women

ICD-10 code

O15

ICD-10 code description

Eclampsia

Primary outcomes

1

Description

homocysteine

Timepoint

before Administration and 36 weeks of gestation

Method of measurement

ELISA method using primary and secondary antibodies by ELISA reader

2

Description

lipoprotein (a)

Timepoint

before Administration and 36 weeks of gestation

Method of measurement

Nephelometric Method by Autoanalyzer

Secondary outcomes

1

Description

LDH

Timepoint

before Administration and 36 weeks of gestation

Method of measurement

Autoanalyzer

2

Description

Urea

Timepoint

before Administration and 36 weeks of gestation

Method of measurement

Autoanalyzer

3

Description

Creatinine

Timepoint

before Administration and 36 weeks of gestation

Method of measurement

Autoanalyzer

4

Description

Platelet

Timepoint

before Administration and 36 weeks of gestation

Method of measurement

Cell counter

5

Description

Urinary creatinine

Timepoint

before Administration and 36 weeks of gestation

Method of measurement

Autoanalyzer

Intervention groups

1

Description

After Administration of folic acid for all the Pregnant women at the dose of 5 mg For 36 week, blood sampling from all the pregnant women Participations before Administration and after 36 weeks of gestation will be taken

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Drug Applied Research Center, Tabriz University of medical Sciences

Full name of responsible person

Dr.Nadereh Rashtchizadeh

Street address**City**

Tabriz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Drug Applied Research Center

Full name of responsible person

Dr. Nadereh Rashtchizadeh

Street address

Department of Biochemistry and Clinical Laboratory, Faculty of Medical science, Tabriz University of Medical science

City

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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

Drug Applied Research Center

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**

Drug Applied Research Center

Full name of responsible person

Dr. Nadereh Rashtchizadeh

Position

PHD of clinical biochemistry/Faculty member

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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