Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Nadereh Rashtchizadeh
Name of organization / entity
Tabriz University of Medical Sciences
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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 wemon 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
Nephlometric 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
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City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Drug Applied Research Center
Full name of responsible person
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Department of Biochemistry and Clinical Laboratory, Faculty of Medical science, Tabriz University of Medical science
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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
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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