

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison study on the effect of prenatal administration of high dose and low dose folic acid on serum RANKL/OPG ratio in pregnancy

Protocol summary

Summary

Objectives: To evaluate the effect of high dose and low dose of folic acid on the levels of soluble receptor activator of nuclear factor - kappa B ligand / Osteoprotegerin ratio during the first trimester of pregnancy. Specific objectives 1- Determining effect of administration of folic acid at high dose (5mg/day until delivery) on serum RANKL/OPG ratio in pregnant women. 2- Determining effect of administration of folic acid at low dose (0.5mg/day until delivery) on serum RANKL/OPG ratio in pregnant women. 3- Determining effect of administration of folic acid at low dose (0.5mg/day until delivery) on serum TNF α levels in pregnant women. 4- Determining effect of administration of folic acid at high dose (5mg/day until delivery) on serum TNF α levels in pregnant women. Practical objectives: To clarify the requirement rate of folic acid in pregnant women to reduce RANKL/OPG ratio and TNF α levels with purpose of reducing the risk of Pre-eclampsia pregnancy Inclusion criteria: Pregnant women, average age of 20 -30 years 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: in single blind randomized clinical trial 88 patients in two similar groups will receive daily from early pregnant until delivery 5 mg/day in group 1 and 0.5 mg/day in group 2. The incidence of hypertension and the laboratory change in the levels of RANKL/OPG ratio and TNF α levels will compare between two study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122315903N1**

Registration date: **2014-07-08, 1393/04/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-08, 1393/04/17

Registrant information

Name

Nadereh Rashtchizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 4666

Email address

rashtchin@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Drug Applied Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-03, 1392/12/12

Expected recruitment end date

2015-03-03, 1393/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison study on the effect of prenatal administration of high dose and low dose folic acid on serum RANKL/OPG ratio in pregnancy

Public title

Comparison study on the effect of prenatal administration of high dose and low dose folic acid on serum

RANKL/OPG ratio in pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Pregnant women with mean of 30-20 years
Exclusion Criteria: 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

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not 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

Tabriz University of medical sciences- Tabriz -Iran

City

Tabriz

Postal code

Approval date

2014-02-12, 1392/11/23

Ethics committee reference number

5/4/11671

Health conditions studied

1

Description of health condition studied

pregnant women

ICD-10 code

O15

ICD-10 code description

Eclampsia

Primary outcomes

1

Description

Osteoprotegerin

Timepoint

Before intervention and 36th week of pregnancy

Method of measurement

ELISA Kit

2

Description

RANKL

Timepoint

Before intervention and 36th week of pregnancy

Method of measurement

ELISA Kit

3

Description

TNF α

Timepoint

Before intervention and 36th week of pregnancy

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Calcium

Timepoint

Before intervention and 36th week of pregnancy

Method of measurement

auto analyzer& Compared with control

2

Description

Phosphorus

Timepoint

Before intervention and 36th week of pregnancy

Method of measurement

auto analyzer& Compared with control

3

Description

Alkaline phosphatase

Timepoint

Before intervention and 36th week of pregnancy

Method of measurement

auto analyzer& Compared with control

Intervention groups

1

Description

High dose group: 44 pregnant women will receive folic acid 5 mg daily from early pregnancy until delivery.

Category

Prevention

2

Description

Low dose group: 44 pregnant women will receive folic acid 0.5 mg daily from early pregnancy until delivery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaykol raeis Clinic

Full name of responsible person

Dr.Nadereh Rashtchizadeh

Street address

Tabriz Universite of Medical Sciences, Shaykholraeis Cilinic

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences- Tabriz- iran

Full name of responsible person

Dr.nadereh rashtchizadeh

Street address

Department of Clinical Biochemistry and Laboratory Medicine,Medical Faculty, Tabriz University of Medical Sciences

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- Tabriz- iran

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, Tabriz University of Medical Sciences

Full name of responsible person

Dr.nadereh rashtchizadeh

Position

phd of clinical biochemistry/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