Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison study on the effect of prenatal administation of high dose and low dose folic acid on surem 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 TNFα levels in pregnant women. 4- Determining effect of administration of folic acid at high dose (5mg/day until delivery) on serum TNFα levels in pregnant women. Practical objectives: To clarify the requirement rate of folic acid in pregnant women to reduce RANKL/OPG ratio and TNFα 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 TNFα 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 administation of high dose and low dose folic acid on surem RANKL/OPG ratio in pregnancy

Public title

Comparison study on the effect of prenatal administation of high dose and low dose folic acid on surem

RANKL/OPG ratio in pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

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

TNFα

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
Other areas of specialty/work
Street address
Department of Clinical Biochemistry and Laboratory Medicine,Medical Faculty, Tabriz University of Medical Sciences
City
Tabriz
Postal code
Phone
+98 411
Fax
Email
rashtchizadeh@rocketmail.com
rashtchin@tbzmed.ac.ir
Web page address

Person responsible for scientific 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
Other areas of specialty/work
Street address
Department of Clinical Biochemistry and Laboratory Medicine,Medical Faculty, Tabriz University of Medical Sciences
City
Tabriz
Postal code
Phone
0068411
Fax
Email
rashtchizadeh@rocketmail.com
rashtchin@tbzmed.ac.ir
Web page address

Person responsible for updating data

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

Other areas of specialty/work

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

City
Tabriz

Postal code

Phone
+98 411

Fax

Email
rashtchizadeh@rocketmail.com
rashtchin@tbzmed.ac.ir

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