

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Multi Minerals (Zn, Mg and Ca) and Vitamins (C and E) Supplementation in the Prevention of Preeclampsia

Protocol summary

Summary

The current study is a controlled randomised clinical trial, is done on pregnant women who referred to the Shahid Mostafa Khomeini hospital, the only Obstetrics and Gynecology training centre in Ilam city, in 2014. 30 patients were assigned to each group. Inclusion criteria include women with at least one of the risk factors for preeclampsia; in the second half of pregnancy. Exclusion criteria included lack of cooperation; intake of multi mineral and vitamin in the control group. The first group receives one tablet multi minerals (Claci-care that contained 800 mg calcium, 200mg magnesium and 8mg zinc) per day, 2. The second group receives 250 mg vitamin C and 55mg vitamin E (one tablet vitamin E and 2 tablets vitamins C per day) 3. The third group was the control group who only receives ferrous sulfate (which is only for pregnant women). After obtaining informed consent and explaining the purpose and importance of the study, the experiment began. The risk factors of preeclampsia will be determined by a specialist. The patients from 20 weeks to 28 weeks of gestation monthly, from weeks 28 to 36 on a fortnightly and then weekly basis until the delivery were visited in Mostafa Khomeini's Hospital for blood pressure and in the Laboratory of Imam Khomeini's Hospital for their proteinuria. Furthermore, 24 hours after giving birth, They will be examined for signs of disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062528617N1**
Registration date: **2016-09-24, 1395/07/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-24, 1395/07/03

Registrant information

Name

Milad Azami

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 938 031 6334

Email address

miladazami@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2015-03-16, 1393/12/25

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Multi Minerals (Zn, Mg and Ca) and Vitamins (C and E) Supplementation in the Prevention of Preeclampsia

Public title

The effects of Multi Minerals (Zn, Mg and Ca) and Vitamins (C and E) Supplementation in the Prevention of Preeclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included women with at least one of the risk factors for preeclampsia (including chronic vascular disease, multiple pregnancy, history of preeclampsia at or near the previous pregnancy, history of thrombophilia or APA syndrome, high maternal age, obesity, etc.); in the second half of pregnancy (20 weeks gestation or later). Exclusion criteria included lack of cooperation; intake of multi mineral and vitamin in the control group.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ilam University of Medical Sciences

Street address

Faculty of Medicine, Ilam University of Medical Sciences, Pazhohesh Boulevard, Ilam

City

Ilam

Postal code

6939177143

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

EC/93/H/223

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O14

ICD-10 code description

O14.9

Primary outcomes

1

Description

The incidence of preeclampsia

Timepoint

The patients from 20 weeks to 28 weeks of gestation monthly, from weeks 28 to 36 on a fortnightly and then weekly basis until the delivery were visited in Mostafa Khomeini's Hospital for blood pressure and in the Laboratory of Imam Khomeini's Hospital for their proteinuria

Method of measurement

Preeclampsia is described with the signs such as the minimum standards hypertension after 20 weeks of pregnancy and proteinuria of ≥ 300 mg per 24 hours or equal to +1 in urine dipstick

Secondary outcomes

empty

Intervention groups

1

Description

The first group receives one tablet multi minerals (Claci-care that contained 800 mg calcium, 200mg magnesium and 8mg zinc) per day. Follow up: The patients from 20 weeks to 28 weeks of gestation monthly, from weeks 28 to 36 on a fortnightly and then weekly basis until the delivery.

Category

Treatment - Drugs

2

Description

The second group receives 250 mg vitamin C and 55 mg vitamin E. Follow up: The patients from 20 weeks to 28 weeks of gestation monthly, from weeks 28 to 36 on a fortnightly and then weekly basis until the delivery.

Category

Treatment - Drugs

3

Description

The third group was the control group who only receives ferrous sulfate (which is only for pregnant women).

Follow up: The patients from 20 weeks to 28 weeks of gestation monthly, from weeks 28 to 36 on a fortnightly and then weekly basis until the delivery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini hospital

Full name of responsible person

Milad Azami

Street address

Faculty of Medicine, Ilam University of Medical Sciences, Pazhohesh Boulevard, Ilam

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Milad Azami

Street address

Faculty of Medicine, Ilam University of Medical Sciences, Pazhohesh Boulevard, Ilam

City

Ilam

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ilam University of Medical Sciences

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

Student Research Committee, Ilam University of Medical Sciences, Ilam, Iran

Full name of responsible person

Milad Azami

Position

Medical Student

Other areas of specialty/work**Street address**

Faculty of Medicine, Ilam University of Medical Sciences, Pazhohesh Boulevard, Ilam

City

Ilam

Postal code

6939177143

Phone

+98 938 031 6334

Fax**Email**

milad98azami@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Medicine,

Full name of responsible person

Khadijeh Pourtaghi

Position

General Physician

Other areas of specialty/work**Street address**

Faculty of Medicine, Ilam University of Medical Sciences, Pazhohesh Boulevard, Ilam

City

Ilam

Postal code

6939177143

Phone

+91 87217728

Fax**Email**

kh.pourtaghi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Student Research Committee

Full name of responsible person

Milad Azami

Position

Medical student

Other areas of specialty/work**Street address**

Faculty of Medicine, Ilam University of Medical Sciences, Pazhohesh Boulevard, Ilam

City

Ilam

Postal code

6939177143

Phone

+98 938 031 6334

Fax**Email**

milad98azami@gmail.com

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