

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of esomeprazole on preeclampsia in pregnant women

Protocol summary

Study aim

The aim of this study is to investigate the effect of esomeprazole on preeclampsia in pregnant women.

Design

This is a double-blind clinical trial study with parallel groups. The patients and the clinical caregiver do not know the type of treatment received by the groups. Using the formation of random blocks of four, the patients are selected and divided into two intervention and control groups. Intervention group: receiving a 40 mg capsule of esomeprazole once a day until the end of the 34th week of pregnancy and group B: receiving a placebo capsule until the end of the 34th week of pregnancy. The study is conducted in phase 3 and on 120 pregnant women diagnosed with preeclampsia. .

Settings and conduct

The site of this clinical trial is Besat Hospital in Sanandaj. The patients using the randomized 4-block method were assigned to two intervention and control groups. The patients and the clinical caregiver were unaware of the blocking and type of treatment and were blinded.

Participants/Inclusion and exclusion criteria

The study's inclusion criteria included patients diagnosed with pre-eclampsia, gestational age between 26 and 32 weeks, absence of abnormalities in the fetus, and fetal weight between 500 and 1800 grams. Exclusion criteria included; eclampsia, chronic hypertension, pulmonary edema, cerebrovascular problems, heart failure, HELLP syndrome, use of proton pump inhibitor drugs, renal failure, disseminated vascular coagulation, fetal distress, and hypersensitivity to proton pump inhibitor drugs.

Intervention groups

In this study, a 40 mg capsule of esomeprazole is prescribed daily until the end of the 34th week of pregnancy for the intervention group. Also, a 40 mg placebo capsule is prescribed for the control group until the end of the 34th week of pregnancy.

Main outcome variables

prolongation of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220928056050N1**

Registration date: **2022-09-30, 1401/07/08**

Registration timing: **prospective**

Last update: **2022-09-30, 1401/07/08**

Update count: **0**

Registration date

2022-09-30, 1401/07/08

Registrant information

Name

Nilofar Azarbayejani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3328 8199

Email address

dr.azarbayejani1990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of esomeprazole on preeclampsia in pregnant

women

Public title

The effect of esomeprazole on preeclampsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preeclampsia diagnosis Gestational age between 26 to 32 weeks Absence of anomalies in the fetus Fetus weight between 500 to 1800 grams

Exclusion criteria:

Eclampsia Chronic blood pressure Pulmonary edema Cerebrovascular problems Heart failure HELLP syndrome The use of proton pump inhibitors Renal failure Diffuse intravascular coagulation Fetal distress Hypersensitivity to proton pump inhibitors

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Using 4 blocks of randomization, patients are selected and divided into two intervention and control groups. AABB, ABAB, ABBA, BBAA, BABA, BAAB,... Group A: one capsule of 40 mg of esomeprazole daily until the end of the 34th week of pregnancy and group B: receive a placebo daily until the end of the 34th week of pregnancy.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. The patients and the clinical caregiver do not know the type of treatment received by the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical

Sciences

Street address

PasdaranSt., Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2022-09-13, 1401/06/22

Ethics committee reference number

IR.MUK.REC.1401.194

Health conditions studied

1

Description of health condition studied

pre-eclampsia

ICD-10 code

O14

ICD-10 code description

Pre-eclampsia

Primary outcomes

1

Description

Prolongation of gestation

Timepoint

Before intervention until delivery

Method of measurement

Using the patient medical record

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, a 40 mg esomeprazole capsule is prescribed daily until the end of the 34th week of pregnancy.

Category

Treatment - Drugs

2

Description

Control group: For the control group, a 40 mg placebo capsule is prescribed daily until the end of the 34th week of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Nilofar Azarbayejani

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Keshavarz St, Besat Hospital, Sanandaj, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

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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

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Nilofar Azarbayejani

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Assistant Professor of Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Nilofar Azarbayejani

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data relating to the main outcomes will be shared.

When the data will become available and for how long

Access to the data is possible six months after the publication of the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Meta-analysis is allowed.

From where data/document is obtainable

Dr. Nilofar Azarbayani via email:

dr.azarbayejani1990@gmail.com

What processes are involved for a request to access data/document

Data will be sent approximately three months after the request.

Comments