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)

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+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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
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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
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Person responsible for updating data

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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