Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The evaluation of esomeprazole efficacy in treatment of early onset pre-eclampsia

Protocol summary

Summary

Objective: Determination of esomeprazole efficacy in treatment of early onset pre-eclampsia. Design: Forty six pregnancy women that suffer to preeclampsia with a gestational age of 26 to 32 weeks are entered in this study. Patients are randomly assigned to two groups according to a random number table generated by the computer. Since this study can be effective in reducing side effects, this study is phase 3. Setting and conduct: This study is a prospective clinical trial, single blind and randomized control group (placebo) that will be performed in the Hospitals of Mashhad University of Medical Sciences onto pregnant women who suffer to preeclampsia with a gestational age of 26 to 32 weeks will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082333680N2**
Registration date: **2017-10-22, 1396/07/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name
Farideh Golhasani
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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golhasanif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of esomeprazole efficacy in treatment of early onset pre-eclampsia

Public title

The evaluation of esomeprazole efficacy in treatment of early onset pre-eclampsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Preeclampsia diagnosis; hypertensive pregnancy; gestational age between 26 to 32 weeks; single-crowned pregnancy; no need to terminate the pregnancy in the next 48 hours; absence of anomalies in the fetus; patient satisfaction for expected treatment; Exclusion criteria: Eclampsia; uncontrolled blood pressure; pulmonary edema; cerebrovascular accidents; heart failure; HELLP syndrome; use of proton pump inhibitors; renal failure; uncertain tests for the evaluation of embryo's health

Age

From **18 years** old to **50 years** old

Gender

Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical sciences
Street address
Mashhad University of Medical Sciences, International Office Administration Center(Qoreishi Building), Daneshgah St.
City
Mashhad
Postal code
9138813944
Approval date
2017-04-18, 1396/01/29
Ethics committee reference number
IR.MUMS.fm.REC.1396.40

Health conditions studied

1

Description of health condition studied
Preeclampsia
ICD-10 code
O15.0
ICD-10 code description
Eclampsia in pregnancy

Primary outcomes

1

Description
Duration of admission to delivery
Timepoint
before intervention until delivery
Method of measurement
Pregnancy termination

Secondary outcomes

1

Description
Frequency of maternal and fetal complications in patients with preeclampsia
Timepoint
before intervention until delivery
Method of measurement
Questionnaire and checklist

2

Description
Biomarker level of tyrosine kinase and endoglycine
Timepoint
after Intervention
Method of measurement
Blood test

Intervention groups

1

Description
The intervention group received 12 mg Betamethasone in two doses every 24 hours plus prescribed 40 mg osmoparazole daily.
Category
Treatment - Drugs

2

Description
The control group received 12 mg Betamethasone in two doses every 24 hours plus prescribed 40 mg placebo daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Seyedeh Azam Pourhoseini
Street address
Department of Obstetrics and Gynecology, Imam Reza Hospital, Taghiabad Square
City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mahyar Mirheidari

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Mashhad University of Medical Sciences, International Office Administration Center(Qoreishi Building), Daneshgah St.

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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
Vice chancellor for research, Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Shourvarzi

Position
Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Department of Obstetrics and Gynecology, Imam Reza Hospital. Taghi-Abad Square,

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Dr. Mirzaeian

Position
Assistant professor of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Farideh Golhasani

Position
Master

Other areas of specialty/work

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golhasanif1@mums.ac.ir

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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