Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of isosorbide dinitrate in preventing of severe pre-eclampsia

Protocol summary

Summary

This study aim was to evaluate the effect of isosorbide dinitrate in the prevention of severe preeclampsia in patients with mild preeclampsia. Twenty seven women with single tone pregnancy with gestational age of 36-26 weeks and the diagnosis of mild preeclampsia were enrolled in the study and were assigned into intervention or control groups. Intervention group received 10 mg of isosorbide dinitrate oral tablet three times a day and the control group received no treatment. Delay in symptoms of severe preeclampsia and gestation duration in both groups were measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809302907N1**
Registration date: **2008-03-20, 1387/01/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2008-03-20, 1387/01/01

Registrant information

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Neda Sahraie

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2008-03-20, 1387/01/01

Expected recruitment end date

2009-05-22, 1388/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of isosorbide dinitrate in preventing of severe pre-eclampsia

Public title

The effect of isosorbide dinitrate in preventing of severe pre-eclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 26-36 gestational week pregnant women, mild pre-eclampsia Exclusion criteria: severe pre-eclampsia symptoms, termination of pregnancy for any reason, uterine contraction, smoking, placenta previa, history of hypertension before 20th week or before the last pregnancy, side effects of isosorbide dinitrate

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

1

Registry name
Non
Secondary trial Id
non
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
cross chamran highway, Hemat highwasy,
City
Tehran
Postal code
Approval date
2009-10-01, 1388/07/09
Ethics committee reference number
13258

Health conditions studied

1

Description of health condition studied
Pre-eclampcia
ICD-10 code
O13
ICD-10 code description
Gestational [pregnancy-induced] hypertension without significant proteinuria Gestational hypertension NOS, Mild pre-eclampsia

Primary outcomes

1

Description
Reduction in blood pressure
Timepoint
daily
Method of measurement
measurement of blood pressure in mmHg

Secondary outcomes

1

Description
pregnancy duration
Timepoint
weekly
Method of measurement
by sonography

Intervention groups

1

Description
isosorbide dinitrate, 10 mg tablet, orally, three times a day
Category
Treatment - Drugs

2

Description
No intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Abadi Hospital
Full name of responsible person
Neda Sahraee
Street address
Molavi street
City
Tehran

2

Recruitment center
Name of recruitment center
Firozgar Hospital
Full name of responsible person
Neda Sahraei
Street address
Vali-e-Asr Square
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Neda Sahraei
Street address
Iran University of Medical Sciences, cross Chamran high way, Hemat highway
City
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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
Iran 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

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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