Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparision of magnesium sulfate and Phenytoin on eclampsia seizure in pregnant women with preeclampsia and eclampsia

Protocol summary

Summary

The aim of this study was to compare the effects of magnesium sulfate with Phenytoin for seizure control in pregnant women with preeclampsia and eclampsia .This randomized, double-blind, single center study wasl conducted in Arash women's hospital. Among singleton pregnant women in the third trimester, 400 of them were participated in this study. Inclusion criteria: preeclampsia (blood pressure >=140/90 and proteinuria) or eclampsia . Participants randomly assigned to two groups. Group I: 4 gram of magnesium sulfate in 100 cc Ringer ,IV, within 15 to 20 minutes. Then, 2 g in 100 cc serum ringer intravenously injected per hour. Group II: 750 mg of phenytoin in 100 cc Ringer intravenously and then table phenytoin 125 mg ,TDS . The two groups were given treatment up to 24 hours after delivery, and if the seizure was ocured,continues for up to 24 hours after seizure. And two groups in terms of seizures and seizure frequency during 48 hours of delivery was assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120311020N7**
Registration date: **2016-12-15, 1395/09/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-15, 1395/09/25

Registrant information

Name

Maryam Khoshideh

Name of organization / entity

Tehran University of Medical Sciences, Arash Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 0909

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran university of Medical sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparision of magnesium sulfate and Phenytoin on eclampsia seizure in pregnant women with preeclampsia and eclampsia

Public title

A comparision of magnesium sulfate and Phenytoin on eclampsia seizure in pregnant women with preeclampsia and eclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: moderate or sever preeclampsia or eclampsia Exclusion criteria: twines pregnancy, history of hypertension or medical disease, history of seizure and neorology problems, smoking and alcohol consumption.

Age

No age limit

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **400**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research, Tehran University of Medical Science
Street address
Dr Masoud Younesian
City
Tehran
Postal code
Approval date
1999-06-02, 1378/03/12
Ethics committee reference number
516

Health conditions studied

1

Description of health condition studied
Seizures
ICD-10 code
O15.2 O15
ICD-10 code description
Eclampsia in the puerperium, Eclampsia in labour

Primary outcomes

1

Description
Seizures
Timepoint
During 48 hours after delivery
Method of measurement
Observation

Secondary outcomes

1

Description
Apgar score
Timepoint
1 minute after delivery
Method of measurement
Observation

Intervention groups

1

Description
Intervention group 1: 4 gram of magnesium sulfate in 100 cc Ringer ,IV, within 15 to 20 minutes. Then, 2 g in 100 cc serum ringer intravenously injected per hour.
Category
Treatment - Drugs

2

Description
Group II: 750 mg of phenytoin in100 cc Ringer intravenously and then table phenytoin 125 mg ,TDS
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Maryam Khoshideh
Street address
Arash women hospital, Rashid street, Resalat highway,Tehranpars
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ethics committee of Tehran University of Medical Science
Full name of responsible person
Dr. Masoud Younesian
Street address
Qods street, Keshavarz boulevard
City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ethics committee of Tehran University of Medical Science
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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Khoshideh
Position
Assistant Professor
Other areas of specialty/work
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Person responsible for updating data

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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