

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

A comparison 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 was 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 $\geq 140/90$ 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 occurred, 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

khooshide@tums.ac.ir

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

Public title

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

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: moderate or severe preeclampsia or eclampsia Exclusion criteria: twines pregnancy, history of hypertension or medical disease, history of seizure and neurology 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
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Position
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Person responsible for updating data

Contact

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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