Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Assessment of the magnesium sulfate effect on the frequency of epilepsy and cesarean section in women with pre- eclampsia

Protocol summary

Summary

This is a randomized, double-blind single-center trial with placebo. The aim of this study is to assess the magnesium sulfate effect on the frequency of epilepsy and cesarean section in women with mild pre- eclampsia in comparison with placebo. Our sample size is 500. All patients with mild preeclampsia are enrolled in study and women with sever preeclampsia, underlying diseases and previous caesarean section are excluded from study. In the first group, 4 grams of magnesium sulfate of 50% solution in 200 cc ringer serum is infused during 20 minuets and then 2 grams magnesium sulfate per hour is injected intravenously and continued up to 24 hours after delivery. In the second group distilled water is infused the same as the first group dosage. Then, seizure and cesarean delivery rates in both groups were compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052111020N5**
Registration date: **2016-10-27, 1395/08/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-27, 1395/08/06

Registrant information

Name
Maryam Khoshideh
Name of organization / entity
Tehran University of Medical Sciences, Arash Hospital
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Zahedan University of Medical Sciences

Expected recruitment start date

2016-11-05, 1395/08/15

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the magnesium sulfate effect on the frequency of epilepsy and cesarean section in women with pre- eclampsia

Public title

Effect of magnesium sulfate on the rate of epilepsy and cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: mild pre- eclampsia; blood pressure between 130-90/ 150-105 mmhg/ mild protein urea
Exclusion criteria: sever pre- eclampsia; blurred vision; sever protein urea; oligurea; impaired liver enzyme; previous cesarean

Age

From **18 years** old to **35 years** old

Gender

Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **500**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Zahedan Uviversity of Medical Sciences
Street address
Khlije Fars boulevard, Zahedan
City
Zahedan
Postal code
Approval date
2007-11-26, 1386/09/05
Ethics committee reference number
1926-86

Health conditions studied

1

Description of health condition studied
preeclampsia
ICD-10 code
O14.0
ICD-10 code description
Gestational Moderate pre-eclampsia

Primary outcomes

1

Description
Epilepcy
Timepoint
After delivery up to 24 hours
Method of measurement
Observational

2

Description
Cesarean section
Timepoint
During delivery
Method of measurement
Observational

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 4 grams of magnesium sulfate of 50% solution in 200 cc ringer serum is infused during 20 minuets and then 2 grams magnesium sulfate per hour is injected intravenously and continued up to 24 hours after delivery.
Category
Treatment - Drugs

2

Description
Control group: Distilled water is infused the same as the first group dosage.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ebne Abitleb Hospital
Full name of responsible person
Dr. Maryam Khooshide
Street address
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Zahedan University of Medical Sciences
Full name of responsible person
Dr. Hooshang Rafighdoost
Street address
Zahedan University of Medical Sciences, Khalij Fars boulevard
City
Zahedan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Zahedan 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
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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