

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

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 0909

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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 University 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

Epilepsy

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 minutes 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 Abitaleb 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

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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