Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of therapeutic regime of magnesium sulfate for 12-hours and 24-hours in postpartum severe preeclampsia

Protocol summary

Study aim
Comparison of the effect of two treatments with magnesium sulfate in preeclampsia
Design
Clinical trial, with parallel, randomized groups, phase 3 on 120 patients with quadruple blockade that was analyzed with Spss software version 24.
Settings and conduct
In this study, 120 mothers with preeclampsia referred to the gynecology and obstetrics ward of Besat Hospital in Sanandaj are evaluated. These individuals are randomly divided into 12-hour intervention group and 24-hour control group treated with magnesium sulfate.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Preeclampsia, 140/90 mm Hg or higher after 20 weeks of gestation, proteinuria with a plus or more Conditions for not entering: Eclampsia, HELLP syndrome
Intervention groups
Patients with preeclampsia are randomly divided into intervention group (12-hour sulfate therapy regimen) and control group (24-hour sulfate therapy regimen).
Main outcome variables
Systolic blood pressure before intervention Diastolic blood pressure before intervention Systolic blood pressure after intervention Diastolic blood pressure after intervention Time to start breastfeeding Time to start oral feeding Foley catheter insertion time Bedtime Ability to breastfeed Need to re-administer magnesium sulfate Incidence of eclampsia Side effects of magnesium sulfate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200503047287N1**
Registration date: **2020-09-02, 1399/06/12**
Registration timing: **prospective**
Last update: **2020-09-02, 1399/06/12**
Update count: **0**
Registration date
2020-09-02, 1399/06/12

Registrant information
Name
Fatemeh Farahani
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-09-22, 1399/07/01
Expected recruitment end date
2021-09-23, 1400/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of therapeutic regime of magnesium sulfate for 12-hours and 24-hours in postpartum severe preeclampsia

Public title
Comparison treatment of magnesium sulfate for 12-hours and 24-hours in preeclampsia
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Preeclampsia Blood pressure 140/90 mm Hg or higher after 20 weeks of gestation Proteinuria with a rate of one plus or more
Exclusion criteria:
Eclampsia HELLP Syndrome

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of individuals to intervention and control groups by quadruple randomization block method: Pregnant mothers with preeclampsia referred to the obstetrics and gynecology ward of Besat Hospital Random assignment of individuals to the intervention and control group: Patients with preeclampsia randomly divided into the intervention group (12 hours) or the control group (24 hours) as follows: Patients are divided into two groups by forming four random blocks: group A (treatment with magnesium sulfate for 24 hours), group B (treatment with magnesium sulfate for 12 hours)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
Pasdaran Blvd

City
Sanandaj

Province
Kurdistan

Postal code
6617713446

Approval date
2020-04-27, 1399/02/08

Ethics committee reference number
IR.MUK.REC.1399.016

Health conditions studied

1

Description of health condition studied
Preeclampsia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
High blood pressure

Timepoint
Hospitalization time and every one hour during magnesium sulfate treatment

Method of measurement
The patient's systolic and diastolic blood pressure is measured every hour by a standard sphygmomanometer.

Secondary outcomes

1

Description
Incidence of seizures: Incidence of involuntary repetitive movements, Complications of magnesium sulfate: which is assessed by spinal reflexes through the patellar reflex, assessment of the number of breaths per minute and the amount of urine collected in the urinbag

Timepoint
Urine output is measured every hour with a Foley catheter

Method of measurement
Using a Foley catheter

Intervention groups

1

Description
Control group: Group A is a control group that includes pregnant mothers with preeclampsia referred to the obstetrics and gynecology ward of Besat Hospital who are being treated with 24-hour magnesium sulfate.

Category
Treatment - Drugs

2

Description
Intervention group: Group B is an intervention group that includes pregnant mothers with preeclampsia referred to the obstetrics and gynecology ward of Besat Hospital who are being treated with 12-hour magnesium sulfate.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Educational Hospital
Full name of responsible person
Nasrin Soofizadeh
Street address
Keshavarz St.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
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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
Sanandaj University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Fatemeh Farahani
Position
Resident
Latest degree
Medical doctor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
At the request of the journal that publishes the article, the data will be provided to the journal.
When the data will become available and for how long
At the time of publication of the article up to six months later
To whom data/document is available
Editor of the journal and academic researchers with the permission of the responsible author
Under which criteria data/document could be used
Only allowed to perform meta-analysis on data.
From where data/document is obtainable
By contacting the responsible author at amirh.brdrn@gmail.com
What processes are involved for a request to access data/document
The application should be sent to the e-mail of the responsible author by sending a resume and the purpose of achieving the research. After reviewing the application, information will be provided to them within a week.
Comments