

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The survey of Magnesium Sulfate in Prevention of Intraventricular Hemorrhage in Premature Infants: Randomization Clinical Trial

Protocol summary

Summary

This study aimed to investigate the effect of magnesium sulfate in infants of mothers with premature rupture of membranes Intraventricular hemorrhage. After confirming the inclusion criteria and obtain the written consent of the individual, individuals one of two groups assigned. Patients were randomly assigned into two groups used of "ran between "order in Excel software and in order to hide the sealed envelopes. Inclusion criteria including, who are have signed a consent form, gestational age 34 weeks, lack of Hypertension, lack of Pre-eclampsia, lack of congenital malformations. Beside the conventional treatments, the intravenous magnesium sulfate will administer in intervention group with dose of 6 gram during 20 to 30 minutes before labor. In comparison group only conventional treatments plus normal saline infusion will using. Finally the neonates in both groups will assessing for intraventricular hemorrhage (IVH) and if necessary the cranial ultrasonography will requested. The sample size this study is 120.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080729223N1**

Registration date: **2016-10-03, 1395/07/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-03, 1395/07/12

Registrant information

Name

Mahsa Rezaei

Name of organization / entity

Iran University of medical Science

Country

Iran (Islamic Republic of)

Phone

+98 66509283

Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2016-02-01, 1394/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey of Magnesium Sulfate in Prevention of Intraventricular Hemorrhage in Premature Infants: Randomization Clinical Trial

Public title

The survey of Magnesium Sulfate in Prevention of Intraventricular Hemorrhage in Premature Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: who are have signed a consent form; Gestational age 34 weeks; Lack of Hypertension; Lack of Pre-eclampsia; Lack of congenital malformations. Exclusion criteria: Lack of consent for enter the study; having hypertension; having pre-eclampsia; having congenital malformations.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Iran University of Medical Science

Street address

Iran, Tehran, Hemat Highway, Milad Tower

City

Tehran

Postal code**Approval date**

2014-06-09, 1393/03/19

Ethics committee reference number

IR.IUMS.rec.1394.9111290015

Health conditions studied**1****Description of health condition studied**

Premature Infants

ICD-10 code

P01.1

ICD-10 code description

Fetus and newborn affected by premature rupture of membranes

Primary outcomes**1****Description**

Intraventricular Hemorrhage

Timepoint

After the birth

Method of measurement

Cranial Ultrasonically

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intravenous Magnesium Sulfate with dose of 6 gram during 20 to 30 minutes

Category

Prevention

2**Description**

Comparison group: without drug

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Akbar Abadi Hospital

Full name of responsible person

Dr. Mahsa Rezaei

Street address

Ferdos s; Molavi st; Tehran; Iran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Ali Javad Musavi

Street address

Vice chancellor for research, Iran University of Medical Sciences

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Mahsa Rezaei

Position

Resident of Obstetrics and Gynecology

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

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