Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Prophylactic effect of magnesium sulfate on intraventricular hemorrhage of very low birth weight neonates

Protocol summary

Summary

The aim of study is to prevent intraventricular hemorrhage by magnesium sulfate in very low birth weight neonates (birth weight ≤1500 grams). In double blind clinical trial 140 very low birth weight (VLBW) will elect. All babies who admit to Imam Reza NICU with birth weight ≤1500 grams and gestational age ≤ 34 weeks included. The babies with major malformation, infection, hemostatic disorder, sever cardio respiratory failure, asphyxia and resuscitation in delivery room will exclude. They randomly will divide in two groups by coin. Intervention group will receive 50% magnesium sulfate, 2.5-5 mg/kg/ day magnesium element via intravenous injection over 15-20 minutes for 3 days. The control group will not take anything. All babies will have a cranial sonography in 24 to 48 hours of life if it be normal will participate in the study. The sonography will repeat at the end of week 1,2and 3 after birth by radiologist who does not knows about intervention. Gestational age, birth weight, sex, five minute apgar score, surfactant usage, blood sugar, anemia, seizure, infection, acidosis, hypoxia, pneumothorax and hypertension will record. Magnesium level will check in day 4 at the end of treatment. Complication of intravenous sulfate magnesium injection includes hypotension, Sinoauricular or atrioventricular conduction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307181162N21**
Registration date: **2013-08-04, 1392/05/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-04, 1392/05/13

Registrant information

Name
Ashraf Mohammadzadeh
Name of organization / entity
Neonatal Research Center of Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1852 1121
Email address
mohamadzadeha@mums.ac.ir

Recruitment status

Recruitment complete

Funding source
Mashhad University of Medical Sciences

Expected recruitment start date

2012-07-04, 1391/04/14

Expected recruitment end date

2013-05-04, 1392/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic effect of magnesium sulfate on intraventricular hemorrhage of very low birth weight neonates

Public title

Prophylactic effect of magnesium sulfate on intraventricular hemorrhage of very low birth weight neonates

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: Neonates who admitted to NICU of Imam Reza Hospital; birth weight ≤ 1500 gm and gestational age ≤ 34 weeks. Exclusion Criteria: major malformation; infection; hemostatic disorder; sever cardio respiratory failure; asphyxia; resuscitation in delivery room
Age
To **28 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **140**
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
Vice chancellor for research of Mashad University of Medical Sciences
Street address
Ghoreshi bilding, Daneshgah street
City
Mashhad
Postal code
Approval date
2012-07-21, 1391/04/31
Ethics committee reference number
9000678

Health conditions studied

1

Description of health condition studied
intraventricular hemorrhage in very low birth weight neonates
ICD-10 code
P52.3
ICD-10 code description
Unspecified intraventricular (nontraumatic) haemorrhage of fetus and newborn

Primary outcomes

1

Description
Intraventricular hemorrhage by brain sonographiy
Timepoint
At first,at the end of week1,2and 3 after birth
Method of measurement
brain sonographiy via anterior fontanle

Secondary outcomes

1

Description
Changing of intraventricular hemorrhage grading
Timepoint
At the end of week 1,2 and 3 after the birth
Method of measurement
brain sonographiy via antrior fontanle

Intervention groups

1

Description
Intervention group: 50% magnesium sulfate, 2.5-5 mg/kg/ day magnesium element via intravenous injection over 15-20 minutes for 3 days
Category
Treatment - Drugs

2

Description
control group will not take anything
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU Imam Reza Hospital , Neonatal Research Center
Full name of responsible person
Dr Ashraf Mohammadzadeh
Street address
Neonatal Research Center, NICU, Imam Reza Hospital
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Gghoreshi bulding, Daneshgah street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Neonatal Research Center
Full name of responsible person
Dr Ashraf Mohammadzadeh
Position
Neonatologist, professor
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