

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

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

Protocol summary

2013-08-04, 1392/05/13

Summary

The aim of study is to prevent intraventricular hemorrhage by magnesium sulfate in very low birth weight neonates (birth weight \leq 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 \leq 1500 grams and gestational age \leq 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 appgar 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

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 \leq 1500 gm and gestational age \leq 34 weeks. Exclusion Criteria: major malformation; infection; hemostatic disorder; severe 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 sonography

Timepoint

At first, at the end of week 1, 2 and 3 after birth

Method of measurement

brain sonography via anterior fontanelle

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 sonography via anterior fontanelle

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 scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Web page address

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