Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of neuroprotective effects of magnesium sulfate on preterm infants with a gestational age of 32-36 weeks

Protocol summary

Study aim
Determination of neuroprotective effects of magnesium sulfate on preterm infants with a gestational age of 32-36 weeks

Design
This study was designed as a randomized, phase 3 clinical trial with a control group and a sample size of 246 and with parallel groups.

Settings and conduct
This study will be carried out at Arash Hospital on pregnant women who have been hospitalized due to spontaneous preterm labor. First, informed consent will be obtained from patients, then demographic, pregnancy and medical questionnaires will be completed. participants will randomly be divided into two groups.: the first group will receive magnesium sulfate and the second group will receive routine care. Type of delivery, gestational age at delivery, neonatal outcomes such as 1 and 5 min Apgar score, respiratory distress, neonatal intensive care unit (NICU) admission, and seizure were recorded. Neurodevelopment will be assessed at the age of four, six, eight, ten, and twelve months using the Ages & Stages Questionnaires (ASQ) questionnaires. These questionnaires will be partially completed by parents and partly by physicians.

Participants/Inclusion and exclusion criteria
All women with spontaneous preterm delivery at the age of 36-32 weeks of gestation will be included and in a case of maternal diseases or fetal abnormalities will be excluded.

Intervention groups
Intervention group: Intravenous infusion of Magnesium sulfate 50%, 2 g per hour for 12 hours Control group: Routine cares (including fetal heart rate monitoring and control of labore progress)

Main outcome variables
Neonatal Neuromotor Development

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120826010664N5**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-26, 1398/10/05**
Update count: **0**

Registration date
2019-12-26, 1398/10/05

Registrant information

Name
Reihaneh Pirjani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of neuroprotective effects of magnesium sulfate on preterm infants with a gestational age of 32-36 weeks

Public title
Magnesium sulfate neuroprotection in preterm infants
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Singleton pregnancy Spontaneous labor Gestational age between 32 and 36 weeks
Exclusion criteria:
Maternal underlying diseases Fetal abnormalities Intrauterine growth retardation (IUGR) Contraindications for use of magnesium sulfate Iatrogenic preterm birth
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **246**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the block randomization method was designed by Stata version 13 software by the epidemiologist. The number of blocks considered is 6. To conceal the random allocation process, 100 treatment cards will be written in sequential order, then the cards will be placed in sealed envelopes. On each envelope, a random 10-digit code will be written with no sequences and a framework that identifies the relevant patient, and only the methodologist will be aware of the code. When the physician announces a patient's eligibility, the methodologist will provide the envelope with the physician, and the treatment will be selected based on the code written in the envelope.
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 Tehran University of Medical Science
Street address
Tehran University of Medical Science, Qods Street, Keshavarz Boulevard
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Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-11-24, 1398/09/03
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.607

Health conditions studied

1

Description of health condition studied
Infant immaturity
ICD-10 code
P07.3
ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
Neurodevelopmental status of infants (including APGAR score, Arterial blood pH after the birth, and Neurodevelopment status after the age of 4 months)
Timepoint
0, 4, 6, 8, 10, and 12 months after the birth
Method of measurement
Blood test and standard Ages & Stages Questionnaires (ASQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One time Intravenous infusion of Magnesium sulfate (made in pasteur institute co, Tehran, Iran) 50% diluted in Ringer lactate serum at a dose of 2 g per hour for 12 hours
Category
Treatment - Drugs

2

Description
Control group: Without intervention (Receiving routine cares including only control of labor progress and fetal

heart rate monitoring)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Dr Reyhaneh Pirjani

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Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Saeideh Zndi

Position

Obstetrics and Gynecology Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Reihaneh Pirjani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available