

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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)

Phone

+98 21 7788 3288

Email address

pirjani@razi.tums.ac.ir

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

City

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Fax

+98 21 7788 3196

Email

pirjani@Razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

Street address

Tehran University of Medical Science, Qods street,
Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Fax

+98 21 8163 3611

Email

rmo@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir/>

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3288

Fax

+98 21 7788 3196

Email

s.zandi2020@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Reihaneh Pirjani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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

City

Tehran

Province

Tehran
Postal code
1653915981
Phone
+98 21 7788 3288
Fax
+98 21 7788 3196
Email
pirjani@razi.tums.ac.ir
Web page address

1653915981
Phone
+98 21 7788 3288
Fax
+98 21 7788 3196
Email
pirjani@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Reihaneh Pirjani
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Eastern 162th St, Baghdarnia st, Resalat Highway,
Tehranpars, Tehran ,Iran
City
Tehran
Province
Tehran
Postal code

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