

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of magnesium sulfate infusion on muscle relaxation after spinal anesthesia for cesarean delivery

Protocol summary

Study aim

Effect of Magnesium Sulfate Infusion on Muscle Relaxation after Spinal Anesthesia for Cesarean Delivery

Design

Randomised, double blinded clinical trial, randomisation was promoted by the method of randomly permuted blocks using Rand software

Settings and conduct

The randomized clinical trial study will conducted on 66 women aged between 18 to 40 years old with term singleton pregnancy candidate for elective cesarean section with epidural analgesia at Al-Zahra hospital of Tabriz University in the period of April 6th, 2017 to September 20th, 2017. Prior to surgery, equally patients will be divided to control and study groups. In operation room, epidural analgesia will be induced in L3-4 or L4-5 intervertebral spaces. Subsequent to delivery and umbilicus clamping, in study group 15 milligrams per kilograms' magnesium sulfate will be infused till end of the operation and in control group same volume of normal saline will be infused. This study will be double blind in which physician and patients are blind to treatment protocols.

Participants/Inclusion and exclusion criteria

Inclusion criteria included term parturient with ASA I or II, 18-40 years age, scheduled for elective cesarean section with spinal anesthesia. Exclusion criteria included parturient who needed emergency cesarean section, had co-existing systemic diseases, any history of psychological disorder, obesity of BMI > 35, history of calcium channel blockers use, recent magnesium consumption, contraindication of spinal anesthesia.

Intervention groups

After neonate delivery in the study group, magnesium sulfate (15 mg kg⁻¹ in 100 ml 0.9% saline) was infused over 15 minutes. Then, 15 mg/kg/hr. of magnesium sulfate were infused until the end of the surgery. In the placebo group, the same volume of 0.9% saline was infused

Main outcome variables

Motor Relaxation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201610037013N14**

Registration date: **2016-10-11, 1395/07/20**

Registration timing: **prospective**

Last update: **2019-07-13, 1398/04/22**

Update count: **1**

Registration date

2016-10-11, 1395/07/20

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 3806

Email address

atashkhoei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-04-06, 1396/01/17

Expected recruitment end date

2017-09-20, 1396/06/29

Actual recruitment start date

2017-04-06, 1396/01/17

Actual recruitment end date

2017-09-20, 1396/06/29

Trial completion date

2017-09-20, 1396/06/29

Scientific title

Effect of magnesium sulfate infusion on muscle relaxation after spinal anesthesia for cesarean delivery

Public title

Magnesium sulfate effect on quality of epidural analgesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

class I or II in American society of anesthesiology; aged between 18-40 years old; term pregnancy; singleton pregnancy; candidate for elective cesarean section; candidate for epidural analgesia.

Exclusion criteria:

emergent cesarean section; systemic diseases (renal, cardiac, pulmonary, hepatic, neuromuscular and etc.) mental disorders body mass index more than 35 kilograms per meter square; calcium channel blockers usage recent use of magnesium; contraindications for epidural analgesia.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will promoted by the method of randomly permuted blocks using Rand software (Rand list online).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double blind in which physician and patients are blind to treatment protocols.

Placebo

Used

Assignment

Parallel

Other design features

Sealed envelope method used for patients randomized assignment to study group

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz Medical University

Street address

Vice chancellor for research, Tabriz university of medical sceinces, Daneshgah square

City

Tabriz

Province

East Azarbaijan

Postal code

516614766

Approval date

2016-10-27, 1395/08/06

Ethics committee reference number

IR.TBZMED.REC.1395.647

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

Epidural analgesia quality

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

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

Muscle relaxation grade

Timepoint

during operation

Method of measurement

will be evaluated by surgeon

2**Description**

patient's comfort grade

Timepoint

during operation

Method of measurement

will be answered by patients

3**Description**

patient's analgesia grade

Timepoint

during operation

Method of measurement

verbal numeric scale

Secondary outcomes

1

Description

serum magnesium level

Timepoint

before operation, 24 hours after operation

Method of measurement

laboratory measurement

2

Description

sensory block duration

Timepoint

after surgery

Method of measurement

physical examination

3

Description

motor block duration

Timepoint

after surgery

Method of measurement

physical examination

Intervention groups

1

Description

Study group: 15 milligrams per kilograms' (approximately 1 gram) magnesium sulfate infusion in 100 milliliters normal saline serum during 15 minutes and subsequently, 15 milligrams per kilograms per hour (approximately 1 gram per hour) infusion till end of the operation.

Category

Treatment - Drugs

2

Description

Control group: Normal saline infusion in same volume of magnesium sulfate infused in study group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Al Zahra Women's Hospital

Full name of responsible person

Dr. Simin Atashkhoyi

Street address

Artesh street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3553 9161

Email

info@alzahraosp.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz Medical University

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of medical sciences, Daneshgah square

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 5921

Email

info@medfac.tbzmed.ac.ir

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

Yes

Title of funding source

Tabriz Medical University

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**

Tabriz Medical University

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Associate Professor, Specialist in Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Medical Education

Street address

Al Zahra hospital, Baghshomal square

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3553 9161

Fax

Email

atashkhoyi@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz medical university

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Associate Professor, Specialist in anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Al Zahra hospital, Baghshomal square

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3553 9161

Fax

Email

atashkhoyi@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz Medical University

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Associate Professor, Specialist in Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Al Zahra hospital, Baghshomal square

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3553 9161

Fax

Email

atashkhoyi@tbzmed.ac.ir

Web page address

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