Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

the efficacy of intravenous midazolam on maternal hemodynamic status and neonatal apgar score in cesarean section under spinal anesthesia

Protocol summary

Study aim

Overall Objective: To determine the effect of intravenous midazolam on maternal hemodynamic status and neonatal Apgar score in cesarean section under spinal anesthesia

Design

A controlled, parallel-group, single-blind, randomized, phase 2-3 clinical trial on 108 patients.

Settings and conduct

After obtaining the approval of the ethics committee, all patients who are candidates for cesarean surgery with spinal anesthesia in Bahlul Gonabadi Hospital will be selected based on the entry criteria. Patients do not know what intervention is being done on them and in which group they are. One group will be injected with midazolam 10 minutes before the start of spinal anesthesia, and the control group will receive conventional treatment. The hemodynamic status of patients in two groups will be monitored during the operation and will be recorded every 5 minutes. After the birth of the baby, Apgar 1 and 5 minutes of the baby will be examined and recorded. The method of performing spinal anesthesia will be the same for all research units. Serum therapy will be the same in all patients.

Participants/Inclusion and exclusion criteria

Entry conditions: pregnant patient candidate for caesarean section with spinal anesthesia, mother's consent, anesthesia class 1 and 2, body mass index less than 35, age range 18 to 45 years, absence of fetal distress. Conditions of non-entry: unfavorable condition of the fetus during pregnancy (fetal distress), severe systemic disease, high blood pressure during pregnancy, emergency caesarean section, presence of any abnormality in the fetus.

Intervention groups

Intervention group: Midazolam will be injected 10 minutes before the start of spinal anesthesia. Control group: will receive the usual treatment, which means they will receive midazolam after the baby is born.

Main outcome variables

Hemodynamic factors; Neonatal Apgar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220501054718N1**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-02, 1401/05/11**
Update count: **0**

Registration date

2022-08-02, 1401/05/11

Registrant information

Name
Arash Hamzeie

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 5725 4222

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2022-10-02, 1401/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
the efficacy of intravenous midazolam on maternal hemodynamic status and neonatal apgar score in cesarean section under spinal anesthesia

Public title
the efficacy of intravenous midazolam on maternal hemodynamic status and neonatal apgar score in cesarean section under spinal anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant patient who is a candidate for cesarean section with spinal anesthesia Mother's satisfaction Term fetus Anesthesia class 1 or 2 Absence of history of mental disorders Body mass index less than 35 No history of preeclampsia Age range 45-18 years Absence of fetal distress No history of eclampsia No history of taking psychotropic drugs Fetus without anomalies

Exclusion criteria:
Improper condition of the fetus during pregnancy (fetal distress) A fetus that is going to be born before the 37th week of pregnancy (preterm) Severe systemic disease (hepatitis, diabetes, Chronic obstructive pulmonary disease(COPD), End-stage kidney disease(ESRD), alcohol dependence) High blood pressure during pregnancy Emergency caesarean section The presence of any abnormality in the fetus History of seizures during pregnancy

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation using permutation blocks. In this way, in the permutation block method of four, the letter A will represent the intervention group and the letter B will represent the control group. There are six possible states in blocks of four ABBA, AABB, BAAB, BBAA, ABAB, BABA, one number will be assigned to each block and each time one number will be selected by lottery and the patients will enter the study in order.

Blinding (investigator's opinion)
Single blinded

Blinding description
Considering that this research compares the results of midazolam injection to the mother before and after the baby is born, a consent form explaining the possible positive and negative effects of midazolam will be given to the patient. However, the patient is not told which of the intervention groups (midazolam injection before the start of the spinal cord) and control (midazolam injection after the baby is discharged) will be placed, and in this sense the patient will be kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Gonabad University of Medical Sciences

Street address
No. 0, Imam Khomeini Street, Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2022-05-07, 1401/02/17

Ethics committee reference number
IR.GMU.REC.1401.033

Health conditions studied

1

Description of health condition studied
Hemodynamic status

ICD-10 code
JB22.0

ICD-10 code description
Delivery by elective caesarean section

2

Description of health condition studied
Neonate Apgar score

ICD-10 code
KB21

ICD-10 code description
Birth asphyxia

Primary outcomes

1

Description

hemodynamic factors

Timepoint

Before starting spinal anesthesia, every 5 minutes during the procedure

Method of measurement

monitoring

2

Description

Neonatal Apgar

Timepoint

The first minute and the fifth minute after birth

Method of measurement

Neonatal Apgar score checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be intravenously injected with midazolam at a bolus dose of 0.02 miligram per kilogram 10 minutes before the start of spinal anesthesia (that is, at the start of fluid therapy). The ampoule of midazolam used in this research is 5 miligram per 1 milliliter and is a product of Tehran Chemical Company, which is diluted with 4 milliliter of distilled water. (concentration 5 miligram per 5 milliliter)

Category

Treatment - Drugs

2

Description

Control group: This group will receive intravenous midazolam with a bolus dose of 0.02 miligram per kilogram after the birth of the baby. (common treatment). The ampoule of midazolam used in this research is 5 miligram per 1 milliliter and is a product of Tehran Chemical Company, which is diluted with 4 milliliter of distilled water. (concentration 5 miligram per 5 milliliter)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Behlool Hospital

Full name of responsible person

Dr. Arash Hamzei

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No. 48, Emam Ali Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Arash Hamzei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
The data related to the main outcome will be shared in the extracted article.
When the data will become available and for how long
After the publication of the results and probably in the winter of 1401
To whom data/document is available
Available to other researchers
Under which criteria data/document could be used
Meta-analysis and related statistical tests
From where data/document is obtainable
Vice Chancellor for Research and Technology of Gonabad University of Medical Sciences
What processes are involved for a request to access data/document
Request to the Vice Chancellor for Research, Referral to the School of Paramedical, Referral to the Department of Anesthesiology and the relevant researcher
Comments