Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Investigating the effect of adding intravenous ketamine to Midazolam in reducing the need for analgesia after spinal anesthesia in elective cesarean section

Protocol summary

Study aim
Determining the effect of adding intravenous ketamine to Midazolam in reducing the need for analgesia after spinal anesthesia in elective cesarean section

Design
Clinical trial with control and parallel groups, randomized and double blind, phase 3 and conducted on 80 patients

Settings and conduct
This study will be conducted on 80 pregnant women referring to Imam Reza, Ghaem and Umm Al-Banin hospitals in Mashhad. In this clinical trial, women are randomly assigned to two different groups using the table of random numbers. In the intervention group, patients are injected with 0.5 mg/kg ketamine and 0.02 mg/kg midazolam in a 2ml syringe during cesarean section after umbilical cord clamping, and in the control group, they are only injected with 0.02 mg/kg midazolam. Pain intensity in patients is measured at 1, 6, 12, and 24 hours after labor. Apgar score of the newborn is measured at minutes 1 and 5 after birth. This study is double blind and the participants as well as the outcome assessors are unaware of the type of intervention and grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women over the age of 18 who have elective cesarean section with ASA I (American Anesthesiology Association). Exclusion criteria: History of trauma to head, addiction and use of psychiatric medication; hallucinations, delusions and hypertension; intracranial hemorrhage; history of ketamine allergy

Intervention groups
Intervention group: In this group, patients are injected with 0.5 mg/kg ketamine and 0.02 mg/kg midazolam in a 2ml syringe during cesarean section after umbilical cord clamping. Control group: In this group, patients are injected only with 0.02 mg/kg midazolam in a 2ml syringe during cesarean section after umbilical cord clamping.

Main outcome variables
Pain intensity, the amount of pain medication used, Apgar score of the newborn

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211013052753N1**
Registration date: **2021-11-14, 1400/08/23**
Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**
Update count: **0**

Registration date
2021-11-14, 1400/08/23

Registrant information

Name
Mitra Samedi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3802 2031

Email address
mitra.samedi@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-16, 1400/08/25

Expected recruitment end date
2022-02-14, 1400/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of adding intravenous ketamine to Midazolam in reducing the need for analgesia after spinal anesthesia in elective cesarean section

Public title

The effect of adding intravenous ketamine to Midazolam in reducing the need for analgesia after spinal anesthesia in elective cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women over the age of 18 who have elective cesarean section with ASA I (American Anesthesiology Association)

Exclusion criteria:

History of trauma to head, addiction and use of psychiatric medication Hallucinations, delusions and hypertension Intracranial hemorrhage History of ketamine allergy

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with the table of random numbers available at ''www.randomization.com'' website will be used. Numbers will be placed in sealed envelopes and these envelopes will place the participants in one of the two groups of control and intervention. An anesthetic technician injects the syringes based on the numbers obtained from the random number table and the envelopes during the cesarean section.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are not aware of the type of treatment and the intervention conducted in each group. That is, the patients are not aware of the type of injection used in each group. Similarly, outcome assessors are unaware of the grouping and the type of injection prescribed for patients in each group. No placebo drug will be used in this study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-05-25, 1400/03/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.119

Health conditions studied

1

Description of health condition studied

Fetal cesarean section

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Pain intensity

Timepoint

At 1,6,12 and 24 hours after labor

Method of measurement

The visual analog scale (VAS) for pain

2

Description

The amount of pain medication used

Timepoint

During the first day after the intervention

Method of measurement

Based on milligrams of Apotel and meperidine used

3

Description
Apgar score of the newborn
Timepoint
Minutes 1 and 4 after birth
Method of measurement
Examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, patients are injected with 0.5 mg/kg ketamine and 0.02 mg/kg midazolam in a 2ml syringe during cesarean section after umbilical cord clamping.
Category
Treatment - Drugs

2

Description
Control group: In this group, patients are injected only with 0.02 mg/kg midazolam in a 2ml syringe during cesarean section after umbilical cord clamping.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Mitra Samedi
Street address
Ghaem hospital, Ahmad Abad blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9176999311
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2

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Mitra Samedi
Street address
Imam Reza Hospital, next to Imam Reza square, Ibne Sina street
City
Mashhad
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3

Recruitment center
Name of recruitment center
Umm Al-Banin Hospital
Full name of responsible person
Mitra Samedi
Street address
Zarrineh Crossroads - Ayatollah Behjat Street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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9177899191
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Email
ramresearch@mums.ac.ir
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
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
Mashhad University of Medical Sciences

Full name of responsible person
Saleheh Asghari

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Saleheh Asghari

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mitra Samedi

Position
resident

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

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mitra.samedi@ymail.com

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
Yes - There is 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
All data can be shared after patients are made unidentifiable.

When the data will become available and for how long
Data can be accessible 6 months after results are published.

To whom data/document is available
Data can be accessible through an email to the corresponding author.

Under which criteria data/document could be used
Data will be available for researchers in universities and other scientific institutes.

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

What processes are involved for a request to access data/document

Carrying out analysis on data is permitted.

Comments