

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 Samedì

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3802 2031

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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

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Umm Al-Banin Hospital

Full name of responsible person

Mitra Samedi

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Zarrineh Crossroads - Ayatollah Behjat Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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

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
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Person responsible for updating data

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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

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