Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of intranasal ketamine on pain intensity after cesarean section

Protocol summary

Study aim

Determining the effect of intranasal ketamine on pain intensity after cesarean section

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 120 patients. For randomization using random allocation method (table of random numbers) are divided into two groups of intervention and control was performed in Imam Hospital of Sari

Settings and conduct

Patients who meet the inclusion criteria are divided into two groups of intervention and control using the method of random allocation (table of random numbers). The study site is Imam Khomeini Hospital in Sari and only the nurse who prepares the drugs from It will be informed and other personnel including the surgeon and anesthesiologist will not be aware of the two groups studied. The drugs will be similar in volume and appearance. Syringes will be marked with numbers 1 and 2 in sealed envelopes.

Participants/Inclusion and exclusion criteria

Admission requirements: Candidate for non-emergency cesarean section, age between 20-35Conditions of non-entry: patient's unwillingness to continue the study at any time, prolongation of cesarean section (more than 1.5 hours), increase in incision length for any reason, any unusual complications during surgery, unstable vital signs History of Cardiovascular Disease andHypertension, History of Mental Disorders, Known Allergy to Ketamine, History of Drug Addiction

Intervention groups

The intervention group will be given 1 mg / Kg of intramuscular ketamine. The control group will be given normal saline as a placebo intranasally.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211011052726N1**
Registration date: **2021-11-08, 1400/08/17**
Registration timing: **retrospective**

Last update: **2021-11-08, 1400/08/17**
Update count: **0**

Registration date

2021-11-08, 1400/08/17

Registrant information

Name

Nafise Faghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

n.faghani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-02-20, 1399/12/02

Actual recruitment start date

2020-10-22, 1399/08/01

Actual recruitment end date

2021-02-20, 1399/12/02

Trial completion date

2021-02-20, 1399/12/02

Scientific title

The effect of intranasal ketamine on pain intensity after

cesarean section

Public title
The effect of intranasal ketamine on pain intensity after cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for non-emergency cesarean section Age between 20-35
Exclusion criteria:
The patient's unwillingness to continue participating in the study at any time Prolongation of cesarean section (more than 1.5 hours) Increased incision length for any reason Occurrence of any unusual complication during surgery Unstable vital signs History of cardiovascular disease and hypertension History of mental disorders Known allergy to ketamine History of drug addiction
Age
From **20 years** old to **35 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation method (table of random numbers) is divided into two groups of intervention and control. Patients in the intervention group will be given 1 mg / kg of intramuscular ketamine. For the control group, normal saline will be administered intravenously as a placebo. 2 will be identified and sealed in envelopes that only the project nurse who prepares the medication will be aware of, and other staff, including the surgeon and anesthesiologist, will not be aware of the two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The syringes were similar in volume and shape, and the syringes were identified by the numbers 0 and 2. Was not given to patients as only The project nurse who prepared the drugs was aware of it, and other staff, including surgeons and anesthesiologists, were unaware of the two groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Mazandaran University of Medical Sciences, Imam Hospital, Sari
Street address
Amir Mazandarani Blvd. Imam Khomeini Educational and Medical Center
City
Sari
Province
Mazandaran
Postal code
33131 - 48166
Approval date
2021-01-27, 1399/11/08
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1400.015

Health conditions studied

1

Description of health condition studied
Severe postpartum pain
ICD-10 code
O80
ICD-10 code description
Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description
Intensity of pain
Timepoint
Enter recovery 15, 30, 60 minutes and 2, 6, 12 hours after surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
Enter recovery 15, 30, 60 minutes and 2, 6, 12 hours after surgery
Method of measurement
Question from the patient (questionnaire)

Intervention groups

1

Description
Intervention group: One 4 mg tizanidine tablet (made by Galenus) is taken orally one hour before the operation and one tablet 24 hours later.
Category
Treatment - Drugs

2

Description
Control group: A dose of 0.4 mg of clonidine (manufactured by Galenus) is taken orally one hour before the operation and 24 hours after the operation.
Category
Treatment - Drugs

3

Description
Control group: One tablet of 0.4 mg placebo is taken orally one hour before the operation and 24 hours after the operation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Nafiseh Faghani Makrani
Street address
Amir Mazandarani Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saedi
Street address
Moalem Ave
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Fax
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Web page address
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Nafiseh Faghani Makrani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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