

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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 20-35 Conditions 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 and Hypertension, 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.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

dr.nfaghani@gmail.com

Web page address

<https://www.mazums.ac.ir>

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

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3325 7230

Fax

+98 11 3325 7230

Email

m.saedi@mazums.ac.ir

Web page address

<https://www.mazums.ac.ir/>

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

Street address

Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

dr.nfaghani@gmail.com

Web page address

<https://www.mazums.ac.ir>

Person responsible for scientific 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

Street address

Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

dr.nfaghani@gmail.com

Web page address

<https://www.mazums.ac.ir>

Person responsible for updating data**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

Street address

Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

dr.nfaghani@gmail.com

Web page address

<https://www.mazums.ac.ir>

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