

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of low dose intravenous ketamine on post operative pain after cesarean section with spinal anesthesia

Protocol summary

Summary

In this study, we have to consider the role of ketamine in decreasing pain and the need for other analgesics including opioid after cesarean section on patients undergoing spinal anesthesia with bupivacaine which is routine method in our hospital. This study is randomized clinical trials on pregnant women who are referring for elective cesarean section and to evaluate the effect of single dose intravenous ketamine in decreasing pain and the need for other analgesics after caesarean section. Patients are divided into two random groups. All patients undergoing spinal anesthesia with bupivacaine by intrathecal injection and 5 minutes after removing the baby, first group receive ketamine 0.25 with slow intravenous injection and group II receive normal saline same amount. The complaint of pain for the first time after cesarean section and also requesting for analgesic will record. For all patients at 1 - 2-6-12 hr postoperative, pain score is measured and ask about the side effects include nausea, vomiting, headache, hallucination, pruritus. During pain score measurement if the pain score was more than five and pain don't relieved with diclofenac suppository then 50mg pethidine intramuscularly will injected, and could repeated up to 3 doses in 24 hours after surgery, at least every 6 hours. All observations recorded and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100611019N1**

Registration date: **2013-07-09, 1392/04/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-09, 1392/04/18

Registrant information

Name

Mojgan Rahmanian

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1444 1022

Email address

rahmanian@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Financial resorces of Semnan University of Medical Sciences

Expected recruitment start date

2012-12-05, 1391/09/15

Expected recruitment end date

2013-07-05, 1392/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low dose intravenous ketamine on post operative pain after cesarean section with spinal anesthesia

Public title

The effect of low dose intravenous ketamine on post operative pain after cesarean section with spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: Singleton pregnancy, semester, elective cesarean section; perform cesarean sections by Fan slices Ashtyl; not having a history of drug abuse; no history of chronic diseases such as diabetes; surgery with spinal anesthesia; no previous surgery; a level of intelligence cooperation; class ASA 1, 2 Exclusion criteria: excessive bleeding during and after surgery; Sensitivity to ketamine; psychological problems (psychotic disorder); contraindication for spinal anesthesia; Hypertension; High Icp; a history of seizures; history of ketamine use and hallucination after that.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 160

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

basij Bolvard

City

Semnan

Postal code

Approval date

2012-08-14, 1391/05/24

Ethics committee reference number

91/16/6184

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes

1

Description

Analgesia

Timepoint

In the first day of study

Method of measurement

Pain Score

Secondary outcomes

empty

Intervention groups

1

Description

All patients received spinal anesthesia (BUPIVACAINE 7-12 mg intrathecally by needle No: 25 at L3-L4 space). Patients were randomly divided into two groups. First group receives Ketamin 0.25 mg/kg intravenously 5 minutes after section. The first time of pain complaint after cesarean section and request for analgesic recorded. If the patient is requested analgesics, Diclofenac as rectal suppository 100mg prescribed and repeated at least every 6 hours up to 4 doses in 24 hours. If pain don't relieved by diclofenac suppository, pethidine 50mg intramuscularly administrated which can repeated at least every 6 hours up to 3 doses in 24 hours after surgery.

Category

Treatment - Drugs

2

Description

After spinal anesthesia as the first group, control group receives salin normal as placebo intrathecally 5 minutes after section. The first time of pain complaint after cesarean section and request for analgesic recorded. If the patient is requested analgesics, Diclofenac as rectal suppository 100mg prescribed and repeated at least every 6 hours up to 4 doses in 24 hours. If pain don't relieved by diclofenac suppository, pethidine 50mg intramuscularly administrated which can repeated at least every 6 hours up to 3 doses in 24 hours after surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Mehri Leysi

Street address

Amir Al Momenin Hospital, Imam Hossein square

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohamad Reza Asgari

Street address

Basij Bolvard

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Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehri Leysi

Position

Obstetrics and Gynecology resident

Other areas of specialty/work

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Research expert

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty