Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of low dose intravenouse 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

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Mojgan Rahmanian
Name of organization / entity
Semnan University of Medical Sciences
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Iran (Islamic Republic of)
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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 intravenouse ketamine on post operative pain after cesarean section with spinal anesthesia

Public title

The effect of low dose intravenouse 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
City
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
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Person responsible for updating data

Contact
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Mehrdad Zahmatkesh
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Research expert
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Web page address

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