Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Scientific title:To study the effect of intravenous low dose ketamin on the severity of pain and the need for analgesics in patients operated with cesarean section with spinal anesthesia in Al-Zahra hospital during2011

Protocol summary

Summary

The objective of this study is to study the effect of low dose intra venous ketamin for decreasing the need for analgesics in patients operated with cesarean section with spinal anesthesia in Al- Zahra hospital. This study will be performed on 60 term single pregnant women in Rasht Al-Zahra hospital. After written and informed consent to participate in the survey, subjects were divided by Block Randomization into two groups (A&B). Control group will be treated with 2cc Normal Saline as placebo and intervention group will be treated with 0.2mg/kg ketamin plus 2cc Normal Saline. Immediately after spinal anesthesia drug of group A or B will be prescribed by an anesthesiologist informed about the kind of drug. After the end of operation in minutes: 0,30,60,90,120,150,180 and hours: 6,12,18,24 , the patient is visited by an assistant who doesn't know the group of patient and pain visual scale (VAS), (That was explained previously for the patient) and the need for analgesic will be evaluated. If the score is up to 5, 200 mg/day diclofenac suppository (maximum 2 dose 100 mg/day) is given and if more analgesic is necessary 50 mg intra muscular pethidine is recommended. The time of the first request of the analgesic, total analgesics used and pain score in mentioned hours is registered. Finally achieved results of relief pain in both groups will be compared by using statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103133485N2**
Registration date: **2011-06-14, 1390/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-14, 1390/03/24

Registrant information

Name
Forozan Milani
Name of organization / entity
Guilan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan university of medical sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Scientific title:To study the effect of intravenous low dose ketamin on the severity of pain and the need for analgesics in patients operated with cesarean section with spinal anesthesia in Al-Zahra hospital during2011

Public title

To study the effect of intravenous low dose ketamin on the severity of pain and the need for analgesics in patients operated with cesarean section with spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria's: 1) Pregnant women with single pregnancy, term, candidate for elective cesarean, 2) Cesarean with pfanenstail incision, 3) No history of drug abuse, 4) Absence of chronic disease such as diabetes mellitus, hypertension, preeclampsia, infection, 5) Surgery performed with the spinal anesthesia by using epinephrined lidocaine, 6) No history of surgery, 7) Having a level of intelligence for optimum cooperation, 8)ASA1 class, 9) Patient with pain score more than 5. Exclusion criteria's: 1) Bleeding after surgery, 2) Definite sensitivity to ketamin, 3) Mental and psychological problems., 4) Contraindication for spinal anesthesia, 5) Past history of hypertension, 6) Increased intracranial pressure. 7) Past history of seizure, 8) Past history of hallucination after ketamin, 9) Class ASA > 1

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethic committee Guilan University of Medical Sciences

Street address

Melat st, Namjoo Ave

City

Rasht

Postal code

Approval date

2011-03-14, 1389/12/23

Ethics committee reference number

35

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

O74.8

ICD-10 code description

Other complications of anaesthesia during labour and delivery

Primary outcomes

1

Description

Determining the effect of low dose intra venous ketamin compared with intra venous Normal saline on the severity of pain and the need for analgesic in cesarean patients with spinal anesthesia.

Timepoint

0,30,60,90,120,150,180 minutes and 6,12,18,24 hours after cesarean

Method of measurement

Pain score in visual scale in 0,30,60,90,120,150,180 minutes and 6,12,18,24 hours after cesarean section, the time of the first request analgesic, total received analgesics

Secondary outcomes

1

Description

Comparing the pain score after surgery in patients with intra venous ketamin versus intra venous Normal saline group

Timepoint

0,30,60,90,120,150,180 minutes and 6,12,18,24 hours after cesarean section.

Method of measurement

Pain visual scale.

2

Description

Determining the relative frequency of hallucination in group with intravenous ketamin

Timepoint

First 24 hours after cesarean section

Method of measurement

According to patient's answers

3

Description

Determining the time point from ending cesarean section to the first dose of analgesic in patients with intra venous

ketamin.

Timepoint

The first 24 hours after cesarean section

Method of measurement

Time of the first request for analgesic (suppository diclofenac)

4

Description

Determining newborn apgar score in group using intra venous Normal saline

Timepoint

First and fifth minutes after birth

Method of measurement

Including 5 sections: heart rate, breathing, effort muscular tone, reflexes, color

5

Description

Comparing the newborn mean apgar in using Normal saline versus intra venous ketamin

Timepoint

First and fifth minutes after birth

Method of measurement

Including 5 sections: heart rate, breathing, effort muscular tone, reflexes, color

6

Description

Determining the relative frequency of complications (vomiting, nausea, headache) in patients using intra venous ketamin

Timepoint

First 24 hours after cesarean section

Method of measurement

Nausea and headache: according to patient’s words.
Vomiting : observation expulsion of content with pressure upper gastro intestinal

7

Description

Determining the relative frequency of complications (vomiting. nausea, headache) in patient by using Normal saline

Timepoint

First 24 hours after cesarean section

Method of measurement

Nausea and headache: according to patient’s words.
Vomiting: Observation expulsion of content with pressure upper gastro intestinal

8

Description

Comparing the relative frequency in group with intra venous ketmin versus intravenous Normal saline

Timepoint

First 24 hours after cesarean section

Method of measurement

Nausea and headache: according to patient’s words.
Vomiting: observation expulsion of content with pressure upper gastro intestinal

9

Description

Determining newborn apgar score in group using intra venous ketamin

Timepoint

First and fifth minutes after birth

Method of measurement

Including 5 sections: heart rate, breathing, effort muscular tone, reflexes, color

10

Description

Determining the time point from ending cesarean section the first dose of analgesic in patients in Normal saline group

Timepoint

The first 24 hours after cesarean section.

Method of measurement

Time of the first request for analgesic (diclofenac suppository)

11

Description

Comparing the time point from ending cesarean section to the first analgesic in group with intra venous ketamin versus intra venous Normal Saline group

Timepoint

The first 24 hours after cesarean section

Method of measurement

Time of the first request for analgesic (Diclofenac suppository)

12

Description

Determining the pain score after surgery in patients with cesarean with spinal anesthesia using intra venous normal saline

Timepoint

,30,60,90,120,150,180 minutes and 6,12,18,24 hours after cesarean section

Method of measurement

Pain visual scale.

13

Description

Comparing the mean dose of pethidine in group with intra venous ketamin versus intra venous Normal saline group.

Timepoint

First 24 hours after cesarean section

Method of measurement

Dose of used pethidine. (mg/kg)

14

Description
Determining the pain score after surgery in patients with cesarean with spinal anesthesia using intra venous ketamin.
Timepoint
0,30,60,90,120,150,180 minutes and 6,12,18,24 hours after cesarean section
Method of measurement
Pain visual scale.

15

Description
Determining the mean dose of used pethidin in group of intra venous ketamin
Timepoint
First 24 hours after cesarean
Method of measurement
Dose of used pethidin. (mg/kg)

16

Description
Determining the mean dose of used pethidin in group of using Normal saline
Timepoint
First 24 hours after cesarean section
Method of measurement
Dose of used pethidin. (mg/kg)

17

Description
Comparing the mean dose of sodium diclofenac suppository in patient using intra venous ketamin versus Normal saline
Timepoint
First 24 hours after cesarean section
Method of measurement
Score more than 5 in pain visual scale.

18

Description
Determining mean dose used sodium diclofenac suppository in the group by using Normal saline
Timepoint
First 24 hours after cesarean
Method of measurement
Number of used suppositories

19

Description
Determining of the mean dose of sodium diclofenac suppository in group using intra venous ketamin
Timepoint
The first 24 hours after cesarean.
Method of measurement
Number of used suppository

Intervention groups

1

Description
2cc Normal saline in control group as placebo
Category
Placebo

2

Description
0.2 mg/kg intra venous ketamin+ 2 cc normal saline in intervention group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital, Guilan University of Medical Sciences
Full name of responsible person
Dr Forozan milani
Street address
Al-Zahra hospital, Namjo street
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasol Sobhani
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Mellat St., Namjoo Ave.
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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
Vice Chancellor for research, Guilan 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
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Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
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