Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of low-dose intravenous ketamine on shoulder pain following caesarean section under spinal anesthesia

Protocol summary

Summary

Background:Prevalence of shoulder pain is more common in cesarian section than natural vaginal delivery, and in cases in which spinal anesthesia is used is more commonly seen. If an anti-pain drug is used before the stimulant, it can reduce severity of pain and usage of painkillers. Ketamine is one of the successful painkillers in reducing pain. This study was performed in order to evaluate effect of low dose ketamine on shoulder pain followed by cesarean section.Inclusion criteria: pregnant women who based on american society of anesthesiologists classification did not have any other organic biochemical or psychiatric disease and were aged between 15-40 years old, and were candidate for selective cesarean section under spinal anesthesia. Exclusion criteria:scientific contraindications(pre-eclampsia,eclampsia,primary hypertension,high intra-cranial pressure due to any cns pathology such as head trauma, brain tumor,recent cerebrovascular accidents),history of addiction,history of allergic reactions to ketamine,history of chronic pain,fracture or trauma to upper limb or shoulder. Methods: In this randomized double-blind study being performed in 2016,a group of 40 pregnant women were selected for intervention and a group of 40 was selected as the control group. All the women met the inclusion criteria. Control group received 5 CC of the pure water as placebo and the second group received 0/5 mg/kg interavenus ketamine in order to evaluate the effect of ketamine in reducing the shoulder pain after cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041627242N2**
Registration date: **2016-07-06, 1395/04/16**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-07-06, 1395/04/16

Registrant information

Name
Manizhe Yousefi moghadam
Name of organization / entity
Sabzevar univerity of medical sciences
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Recruitment status

Recruitment complete

Funding source

Sabzevar University Of Medical Sciences

Expected recruitment start date

2016-04-18, 1395/01/30

Expected recruitment end date

2016-08-27, 1395/06/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low-dose intravenous ketamine on shoulder pain following caesarean section under spinal anesthesia

Public title

The effect of low-dose intravenous ketamine on shoulder pain

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: pregnant women wich age is between 15-40 ywers old, and will be c/s under spinal anastesia
Exclusion criteria: Interdict scientific forbide(rise ICP; eklampsy; pereklampsy; head truma; primery hypertension; brain tumor;cerebrovascular accsident in past); addiction; sensivity to ketamine; cronic shulder pain; history of psychiatric disease; pregnancy hypertension; history of fracture;

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Sabzevar Univercity Of Medical Science

Street address
Setad Markazi,besid the Heshmatieh hospital,Asadabadi street,Sabzevar

City
Sabzevar

Postal code

Approval date
2015-08-03, 1394/05/12

Ethics committee reference number
ir.medsab.rec.1394.63

Health conditions studied

1

Description of health condition studied
The effect of ketamin on shoulder pain

ICD-10 code
y48.2

ICD-10 code description
Other and unspecified general anaesthetics

Primary outcomes

1

Description
Shoulder pain

Timepoint
After intervention in first 24 hour

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Hallucination

Timepoint
After interventin in first 3 hour

Method of measurement
Taking history

Intervention groups

1

Description
All the patients in the intervention group receive 500-1000 cc of ringer before performing spinal anesthesia.Before spinal anesthesia standard monitoring including blood pressure(systolic and diastolic),heart rate and pulse oxymetry is performed for the intervention group.Spinal anesthesia is performed by 2.5 cc bupivacaine and hyperbaric oxygen 0.5% .The intervention group receives ketamine 2/0 mg/kg iv after spinal anesthesia and before performing the cesarian section. Ketamin and pure water are stored in same 5 cc syringes and are coded by the technician.The anesthesiologist and the technician are not aware of consistence of the syringes.

Category
Treatment - Drugs

2

Description
All the patients in control group receive 500-1000 cc of ringer before performing spinal anesthesia.Before spinal anesthesia standard monitoring including blood pressure(systolic and diastolic),heart rate and pulse oxymetry is performed for the control group.Spinal anesthesia is performed by 2.5 cc bupivacaine and hyperbaric oxygen 0.5%.The control group receives 5 cc of pure water. Ketamin and pure water are stored in same 5 cc syringes and are coded by the technician.The anesthesiologist and the technician are not aware of consistence of the syringes.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sabzevar Shahidane Mobini hospital
Full name of responsible person
Solmaz Dastras
Street address
number 10 aref street
City
sabzevar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mohamad Mohamadzade
Street address
Mobini hospital, Kashefi street
City
sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Solmaz dastras
Position
Bacheller
Other areas of specialty/work
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Person responsible for scientific inquiries

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Anesthiologist
Other areas of specialty/work
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+98 51 4423 8100
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Email
Yousefim1@medsab.ac.ir
Web page address

Person responsible for updating data

Contact

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