Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Analgesic effects of subcutaneous of low dose Ketamine before and after cesarean section surgery

Protocol summary

Summary

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a double-blind prospective, randomized study will be done among patients with Elective Cesarean Section. Spinal anesthesia with 12.5 mg Marcaine will done in both groups equally. Inclusion criteria: - The patient's satisfaction – Age between 20 and 40 years old - ASA class I & II Exclusion criteria: - The lack of patient's satisfaction to spinal anesthesia - History of hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol- dependency - Contraindication of Ketamine - Contraindications of Spinal Anesthesia(Patient refusal ; Infection at the site of planned needle puncture ; Elevated intracranial pressure and Bleeding diathesis) Patients will be randomly allocated into three groups according to table of random numbers. Groups "one", "two", and "three" will receive 0.5 mg/kg of ketamine with 10 ml Normal Saline Before surgery incision in place of incision Subcutaneously, 0.5 mg/kg of ketamine with 10 ml Normal Saline after end of surgery in place of incision Subcutaneously, and 10 ml Normal Saline after end of surgery in place of incision Subcutaneously, respectively. Postoperative pain and needs for analgesics will measured at 1,2,4,6,12,18 and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022012539N1**
Registration date: **2013-08-17, 1392/05/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-08-17, 1392/05/26

Registrant information

Name
Mehdi Aslani
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 1222 0198
Email address
aslani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic effects of subcutaneous of low dose Ketamine before and after cesarean section surgery

Public title

Analgesic effects of subcutaneous of low dose Ketamine before and after cesarean section surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: - The patient's satisfaction – Age between 20 and 40 years old - ASA class I & II Exclusion criteria: - The lack of patient's satisfaction to spinal anesthesia - History of hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol- dependency - Contraindication of Ketamine - Contraindications of Spinal Anesthesia(Patient refusal ; Infection at the site of planned needle puncture ; Elevated intracranial pressure and Bleeding diathesis)

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

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
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
No.12, Chamber Sadaf, Golestan Blvd

City
Ahvaz

Postal code
6135733777

Approval date
2012-12-19, 1391/09/29

Ethics committee reference number
ETH-641

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
R52.0

ICD-10 code description
Acute Pain

Primary outcomes

1

Description
Pain

Timepoint
1,2,4,6,12,18 and 24 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Opioid Consumption

Timepoint
24 hours after surgery

Method of measurement
Milligram

Intervention groups

1

Description
Drugs: 1-Ketamine: Dose: 0.5mg/kg Number of using: Once Factory name: Rotex medica Manufacturing Country's Name: Germany Location prescribed: In place of incision Subcutaneously Administration time: Before surgery incision 2- Normal Saline: Dose: 10 ml Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: In place of incision Subcutaneously Administration time: Before surgery incision

Category
Treatment - Drugs

2

Description
Drugs: 1-Ketamine: Dose: 0.5mg/kg Number of using: Once Factory name: Rotex medica Manufacturing Country's Name: Germany Location prescribed: In place of incision Subcutaneously Administration time: After end of surgery 2- Normal Saline: Dose: 10 ml Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: In place of incision Subcutaneously Administration time: After end of surgery

Category
Treatment - Drugs

3

Description
Drug: Normal Saline Dose: 10 ml Number of using: Once

Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: In place of incision Subcutaneously Administration time: After end of surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Educational Hospital

Full name of responsible person

Dr. Kaveh Behaeen

Street address

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

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, Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mehdi Aslani

Position

Resident of Anesthesia

Other areas of specialty/work

Street address

No. 12, Enghelab Chamber, Golestan Blvd

City

Ahvaz

Postal code

6135786955

Phone

+98 61 1332 5869

Fax

+98 86113325478

Email

aslani.m@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mehdi Aslani

Position

Resident of Anesthesia

Other areas of specialty/work

Street address

No. 12, Enghelab Chamber, Golestan Blvd

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Fax

+98 86113325478

Email

aslani.m@ajums.ac.irfatahi.m@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

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Ahvaz Jundishapur University of Medical Sciences

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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