Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of therapeutic effect of intravenous ketamine low doses versus pethidine on post spinal anesthesia shivering in patients undergoing elective cesarean section

Protocol summary

Summary

The overall goal: Comparison of therapeutic effect of intravenous ketamine low doses versus pethidine on post spinal anesthesia shivering in patients undergoing elective cesarean section. Study design: random double blind Placebo controlled. Study population: the study population consisted of patients who were referred for elective cesarean Best Hospital operating room. Inclusion Criteria: being candidate for cesarean section; fill in consent forms; physical status class I or II in accordance with anesthesia. Exclusion Criteria: pregnancy associated with diseases such as hypertension, diabetes; heart valve disease; coronary artery disease; pulmonary hypertension;pre Eclampsia and Diabetes mellitus. Sample size and sampling: with respect to Type I error of 5%, power of 90%, 45%, and the incidence of shivering in a group of 25 patients in the placebo group versus 85% in this study, 45 patients in each group were calculated for each group examines Intervention or interventions studied: Pethidine group of 5/0 3 kg and ketamine / kg in a volume equal to 0 immediately after spinal anesthesia is injected intravenously. Presence or absence of chills and grade them 4-0 is determined based on.Grade zero: no chills. Grade1: mild fasciculation in the face and neck. Grade2: trembling visible muscle groups in more than one category. Grade 3: Zlany activity of the whole body is involved. Intervention: the drug intravenously then Immediately after injection of spinal anesthetic is injected. Then chill after surgery to assess patient access to measures of pain occurs. Primary outcome or outcomes studied: during surgery and recovery Any adverse effect if seen is recorded Adverse events (nausea, vomiting, nystagmus, hypotension requiring treatment, bradycardia requiring medication).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100214860N1**
Registration date: **2013-10-25, 1392/08/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-25, 1392/08/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research Office of Kurdistan University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of therapeutic effect of intravenous ketamine low doses versus pethidine on post spinal anesthesia shivering in patients undergoing elective cesarean section

Public title
Davy effects of pethidine and ketamine in preventing postoperative shivering after cesarean section in pregnant women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: being candidate for cesarean section; fill in consent forms; physical status class I or II in accordance with anesthesia. Exclusion Criteria: pregnancy associated with diseases such as hypertension, diabetes; heart valve disease; coronary artery disease; pulmonary hypertension;pre Eclampsia and Diabetes mellitus.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Informed consent was obtained from patients undergoing elective cesarean section patients are being enrolled. Vblafaslh drug intravenously after spinal injection is administered. Presence or absence of chills and grade will be determined based on a 4-0 scale.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kurdistan University of Medical Sciences
Street address
Kurdistan University of Medical Sciences, Opposite Hotel Shadi, Campus
City
sanandaj
Postal code
66177-13446
Approval date
2013-08-06, 1392/05/15
Ethics committee reference number
MUK.REC.1392.10

Health conditions studied

1

Description of health condition studied
Shivering after spinal anesthesia in patients undergoing elective cesarean surgery.
ICD-10 code
074.6
ICD-10 code description
Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description
Shivering after spinal anesthesia in patients undergoing elective cesarean
Timepoint
Since spinal anesthesia or intravenous pethidine or ketamine
Method of measurement
Presence or absence of chills and grade them 4-0 is determined based on.Grade zero: no chills. Grade1: mild fasciculation in the face and neck. Grade2: trembling visible muscle groups in more than one category. Grade 3: Zlany activity of the whole body is involved.

Secondary outcomes

1

Description
Adverse events (nausea, vomiting, nystagmus, hypotension requiring treatment, bradycardia requiring medication
Timepoint
Any complications during the surgery and recovery if the questionnaire is
Method of measurement
Based on history and physical examination and observation

Intervention groups

1

Description

Pethidine group of 0/5 kg ketamine group and 0/3 kg at equal volume immediately after spinal anesthesia is injected intravenously. Two groups of disposable needles for anesthetic drug bupivacaine 24 and 12 mg dose is used.

Category

Treatment - Drugs

2

Description

In control group, 24 disposable needles for anesthetic drug bupivacaine and 12 mg dose is used unlike the intervention group but no drug (ketamine or pethidine) for prevention of shivering after cesarean section are not receiving.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr. karim naseri

Street address

Vakili cross road

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Office of Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Ataolah Haydari

Street address

Kurdistan University of Medical Sciences

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Office of Kurdistan 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

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Full name of responsible person

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Position

Medical Student

Other areas of specialty/work

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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