

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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

##### Name

Arman Sarshivi

##### Name of organization / entity

Kurdistan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Arman Sarshivi

**Position**

Medical Student

**Other areas of specialty/work****Street address**

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Anesthesiologist

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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*