# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jul 2026

## The Effectiveness of low dose Ketamine and Propofol in prevention of Shivering in Patients during Sesarean section under Spinal Anesthesia

## Protocol summary

**Study aim**
The aim of this study is to compare the effectiveness of low dose Ketamine and Propofol in Prevention of Shivering in Patients during Cesarean Section under Spinal Anesthesia

**Design**
Clinical trial with control group with parallel groups, Triple blind, randomized, and sample size is 132.

**Settings and conduct**
In this study 132 patient with elective Cesarean section with spinal anesthesia were included and will be divided into three groups of 44. All patients with marcaine 0.5% undergo spinal anesthesia.The Ketamine group will receive 10 mg of ketamine, Propofol group, 10 mg of propofol and 2 ml of Normal saline in placebo group immediately after embryo withdrawal.For blindness the volume of injectable solution will be 2 cc in each of three groups.The preparing of drugs is done by an anesthetic technician who is not involved in this study and for injection is given to someone who is unaware of contents of the syringes.A person who is unaware of the type of injectable drug evaluate the shivering of patients during and 0.5 h after operation in recovery room and records the results.Nausea and vomiting of patients are also recorded in these times.The date analysis in this study is done by person who in unaware of the type of drug used.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria are pregnant women aged 15_45 years old; patients with ASA class I & II; patients signed informed consent and exclusion criteria are history of allergy to Ketamine and Propofol; placenta previa; preeclampsia & eclampsia; Raynaud's syndrome; thyroid diseases and cardiovascular diseases.

**Intervention groups**
The ketamine group will receive 10 mg of ketamine, Propofol group, 10 mg of propofol and 2 ml of normal saline in placebo group immediately after embryo withdrawal. The injectable solution will be equal to 2 cc in each of the three groups.

**Main outcome variables**
Shivering in patients during cesarean section

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20180930041181N1**
Registration date: **2018-10-22, 1397/07/30**
Registration timing: **prospective**

Last update: **2018-10-22, 1397/07/30**
Update count: **0**

**Registration date**
2018-10-22, 1397/07/30

**Registrant information**
**Name**
Faezeh Javidnia
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-11-22, 1397/09/01
**Expected recruitment end date**
2019-01-20, 1397/10/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The Effectiveness of low dose Ketamine and Propofol in prevention of Shivering in Patients during Sesarean section under Spinal Anesthesia

**Public title**
Effect of Ketamine & Propofol in prevention of Shivering

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Pregnant Women aged 15_45 years old Patients signed informed consent Patients with ASA class I & II

**Exclusion criteria:**
History of previous allergy to Ketamine & Propofol Placenta Previa Preeclampsia and eclampsia Raynaud's Syndrom Thyroid disease Cardiovascular disease Psychological Problems Body temperature < 36 or > 38 Parturients with ASA class III or high

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

**Gender**
Female

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**
Target sample size: **132**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
A Convenient Sampling method will be used to enter the patients.These patients will be randomly assigned into three groups: Ketamine, Propofol and Placebo.The randomization tool will be Opaque envelopes in this study.For randomization three type of envelopes to the number of sample size is provided, an envelope randomly selected from the envelopes and based on the type of envelope code selected (type A, B and C )the prescribed drug for each code will be injected to patients.Preparing of these three drugs is done by an anesthetic technician who is not involved in this study and for injection is given to someone who is unaware of contents of the syringes.In the Ketamine group, 10 mg of ketamine and in the Propofol group, 10 mg of Propofol and 2 ml of Normal Saline will be injected in the Placebo group.For blindness the volume of injectable solution will be 2 cc in each of three groups.

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
Preparing of these three drugs is done by an anesthetic technician who is not involved in this study and for injection is given to someone who is unaware of contents of the syringes.In the Ketamine group, 10 mg of ketamine and in the Propofol group, 10 mg of Propofol and 2 ml of Normal Saline will be injected in the Placebo group.For blindness the volume of injectable solution will be 2 cc in each of three groups.A person who in not aware of the type of injectable drug evaluate patients during and after surgery. The data analyst in this study will also be unaware of the type of drug used.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Ardebil University of Medical Sciences

**Street address**
Ardebil University of Medical Sciences

**City**
Ardebil

**Province**
Ardabil

**Postal code**
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**Approval date**
2018-01-14, 1396/10/24

**Ethics committee reference number**
IR.ARUMS.REC.1396.203

## Health conditions studied

### 1

**Description of health condition studied**
Postoperative Shivering

**ICD-10 code**
T88.5

**ICD-10 code description**
Other complications of anesthesia

## Primary outcomes

### 1

**Description**
Shivering

**Timepoint**
During and after surgery

**Method of measurement**
Shivering score (0_4)

## Secondary outcomes

### 1

**Description**
Nausea and vomiting
**Timepoint**
During and after surgery
**Method of measurement**
Nausea and vomiting Score (1_4)

## Intervention groups

### 1

**Description**
Intervention group: 10 mg Ketamine immediately after embryo out
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: 10 mg Propofol immediately after embryo out
**Category**
Treatment - Drugs

### 3

**Description**
Control group: 2 cc Normal Saline
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Alavi hospital
**Full name of responsible person**
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## Sponsors / Funding sources

### 1

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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**
Ardabil University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available