Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country

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
۸۵۹۹۱۵۶۱۸۹
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
Faezeh Javidnia
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Alavi hospital., Shahid Moadi Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

Contact
Name of organization / entity
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Position
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Person responsible for updating data

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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