Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of Ketamine, Tramadol and Ondansetron on prevention of shivering due to Spinal Anesthesia in cesarean section surgery

Protocol summary

Study aim
Introduction and utilization of an effective, uncomplicated method and suitable replacement for pethidine to control shivering in spinal anesthesia in cesarean section

Design
A double-blinded and randomized clinical trial with parallel groups design of 508 patients

Settings and conduct
This study will be done as a clinical trial in Alzahra Hospital in Rasht. All patients will have at least 8 hours of fasting. Before performing anesthesia, hemodynamic variables, operating room temperature, and central temperature of patients will be recorded. Spinal anesthesia will be performed with 12.5 milligrams isobar marcaine on lumbar spine 3 and 4. If despite receiving these medications, patients experience shivering in Grades 3 and 4, they will receive 25 milligrams pethidine after clamping the cord. Cases of repeated shivering, cases that receive pethidine, the intensity of postoperative shivering and minute one and five Apgar score of babies will be recorded. In this study, the intensity of shivering will be recorded every 5 minutes during operation time and every 15 minutes in 45 minutes of recovery time(3 times). Drugs will be prepared and coded by an anesthetic technician, not included in the research. Patients, the responsible anesthetist, and the person who records signs are blind.

Participants/Inclusion and exclusion criteria
Entry criteria: pregnant women candidate for cesarean section under spinal anesthesia, ASA Class I, II and, age 18-39 Non-entry criteria: a history of allergy or prohibition for each of studied drugs, addiction, heart disease, liver, and kidney dysfunction.

Intervention groups
ketamine group (0.2 milligrams per kilogram intravenous), tramadol group (0.5 milligrams per kilogram intravenous), Ondansetron group (4 milligrams intravenous), control group (5 milliliters normal saline)

Main outcome variables
Shivering intensity based on the used drug, Apgar minute one and five

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110425006281N2**
Registration date: **2018-12-29, 1397/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**
Update count: **0**

Registration date
2018-12-29, 1397/10/08

Registrant information

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Ali Mohammadzadeh Jouryabi

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
2019-03-21, 1398/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of Ketamine, Tramadol and Ondansetron on prevention of shivering due to Spinal Anesthesia in cesarean section surgery

Public title
Comparison of Ketamine, Tramadol, and Ondansetron in shiver controlling
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women Candidates for cesarean section Under spinal anesthesia ASA class I, II Age between 18-39
Exclusion criteria:
History of allergy Prohibition for each of the studied drugs Addiction to any chemical or natural compound Psychosis Having cold Heart disease Liver and kidney dysfunction History of seizure History of using Monoamine Oxidase inhibitor in the past 14 days Severe asthma Respiratory depression The initial temperature of the patient`s body is above 38 Celsius or the central temperature is less than 36 Celsius Getting any medication that changes the thermoregulation Weight over 100 Kilograms and below 50 Kilograms History of using vasodilator Cases requiring sedation or having intravenous administration due to partial spinal anesthetics A condition that temperature cannot be maintained due to equipment problems in heating and cooling systems
Age
From **18 years** old to **39 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **508**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized with quadruple blocks and divide into four groups of a low dose of ketamine=A, tramadol=B, Ondansetron=C, and control=D. The randomization unit is individual. In this randomization, we do not have a layer and we use a random numbers table tool. The method of constructing a random sequence is as follows: ABCD-ABDC-ACBD-ACDB-ADBC-ADCB-BACD-BADC-BDCA-BDAC-BCAD-BCDA--CABD-CADB-CBAD-CBDA-CDAB-CDBA-DABC-DACB-DCAB-DCBA-DBAC-DBCA-ABCD-ABDC-ACBD-ACDB-ADBC-ADCB-BACD-BADC-BDCA-BDAC-BCAD-BCDA-CABD-CADB-CBAD-CBDA-CDAB-CDBA-DABC-DACB-DCAB-DCBA-DBAC-DBCA-ABCD-ABDC-ACBD-ACDB-ADBC-ADCB-BACD-BADC-BDCA-BDAC-BCAD-BCDA-CABD-CADB-CBAD-CBDA-CDAB-CDBA-DABC-DACB-DCAB-DCBA-DBAC-DBCA-ABCD-ABDC-ACBD-ACDB-ADBC-ADCB-BACD-BADC-BDCA-BDAC-BCAD-BCDA--CABD-CADB-CBAD-CBDA-CDAB-CDBA-DABC-DACB-DCAB-DCBA-DBAC-DBCA-ABCD-ABDC-ACBD-ACDB-ADBC-ADCB-BACD-BADC-BDCA-BDAC-BCAD-BCDA-CABD-CADB-CBAD-CBDA-CDAB-CDBA-DABC-DACB-DCAB-DCBA-DBAC-DBCA-ABCD-ABDC-ACBD-ACDB-ADBC-ADCB-BACD After providing the list, we will give it to the anesthetic technician to categorize patients in control or treatment groups based on the above list.
Blinding (investigator's opinion)
Double blinded
Blinding description
All drugs and placebo (normal saline) are prepared by an anesthetic technician who is not included in this study and will be coded in 5-millimeter syringes and will be given to the responsible anesthetist. So, In the event of complications (drowsiness, nausea, vomiting, itching, flushing, and hallucination), it will be clear which patient belongs to which Group and if necessary, it will be treated based on the type of complication. Accordingly, patients, the anesthetist, and the trained person recording items listed in the questionnaire (severity of shivering, Apgar minute one and five and vital signs of patients) are unaware of the type of treatment group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Guilan University Of Medical Sciences
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144666949
Approval date
2018-09-01, 1397/06/10
Ethics committee reference number
IR.GUMS.REC.1397.208

Health conditions studied

1

Description of health condition studied
Shivering Complication in Spinal Anesthesia in Cesarean Section
ICD-10 code
O74.6
ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
Severity of shivering
Timepoint
Every 5 minutes during surgery and every 15 minutes in 45 minutes of recovery time, the intensity of shivering will be recorded.
Method of measurement
Shivering classification table

2

Description
Baby`s Apgar Minute One and five
Timepoint
Minute one and five of baby's birth
Method of measurement
Based on Apgar Assessment Table

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: low dose of ketamine (0.2 milligrams per Kilogram intravenous), (500 milligrams per 10 milliliters of the Stroup pharmaceutical company in Belgium). Immediately after spinal anesthesia, it will be injected to patients.
Category
Prevention

2

Description
Intervention group Tramadol (0.5 milligrams per Kilogram intravenous), (50 milligrams per milliliters, Drugpakhsh Pharmaceutical Company). Immediately after spinal anesthesia, it will be injected to patients.
Category
Prevention

3

Description
Intervention group Ondansetron (4 milligrams intravenous), (4 milligrams in 2 milliliters produced by Borujerd-Iran General Purpose Pharmacy Company).Immediately after spinal anesthesia, it will be injected to patients.
Category
Prevention

4

Description
Control group: 5 milliliters of normal saline will be injected to patients, immediately after spinal anesthesia.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr Gelareh Biazar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Vice Chancellor for research of Guilan university of medical sciences
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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
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Dr Ali Mohammadzadeh Joryabi

Position
Associate Professor of Cardiac Anesthesiology

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Associate Professor of Cardiac Anesthesiology

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Research Expert

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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