Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of intravenous injection of Ketamine and Ondansetron in the prevention of the post-operative shivering in Cesarean Section under spinal anesthesia

Protocol summary

Study aim

Comparison of the effect of prophylactic injections of ketamine and Ondansetrone on shivering after cesarean section under spinal anesthesia

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 121 patients. Randomization is done using Random Allocation software.

Settings and conduct

This is a randomized double-blind clinical trial in which the target population of pregnant women is candidates for cesarean section under spinal anesthesia at Beheshti Hospital in Isfahan. Patients are randomly assigned to three groups C, B, and A, and each group is randomly assigned to one of three intervention groups, and the patient's vital signs are monitored before, during, and after surgery. The intervention groups are coded, so the injecting person, the clinical caregiver, and the patient are unaware of the injected intervention and are blind.

Participants/Inclusion and exclusion criteria

Pregnant women in grades I and ASA II, candidates for cesarean section under spinal anesthesia, can be screened if they have no history of high blood pressure, mental illness, heart problems with EF <60%, or kidney problems with GFR <60.

Intervention groups

Intervention group A: 4 mg of Ondansetron, Intervention Group B; 0.5 mg of ketamine per kilogram of body weight and C intervention group; Normal saline as a placebo is injected into the patient immediately after clamping of the umbilical cord.

Main outcome variables

Shivering

General information

Reason for update

Adress changing

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N20**
Registration date: **2020-06-10, 1399/03/21**
Registration timing: **prospective**

Last update: **2022-07-30, 1401/05/08**
Update count: **1**

Registration date

2020-06-10, 1399/03/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of intravenous injection of Ketamine and Ondansetron in the prevention of the post-operative shivering in Cesarean Section under spinal anesthesia

Public title
Ketamine and Ondansetron in post operative shivering in Cesarean Section

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women are candidates for cesarean section Candidates for Spinal anesthesia ASA class I and II The patient's consent to participate in the study

Exclusion criteria:
History of high blood pressure History of mental illness History of heart problems with EF <60% History of kidney problems with GFR <60

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **121**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done in a simple way so that the names of patients enter the randomization software (https://random-allocation-software.software.informer.com/2.0/) if they have the necessary conditions and according to the time of entry. software Randomly assign numbers to each patient, and based on these numbers, patients enter one of the intervention or control groups so that their number reaches the required number in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs and placebo are packaged in the same form with the same volume and coded, and are randomly distributed among patients so the attending, the clinical caregiver, and the evaluator do not notice the type of medication.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib Street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2017-06-18, 1396/03/28

Ethics committee reference number
IR.MUI.REC.1396.3.028

Health conditions studied

1

Description of health condition studied
Postoperative shivering

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
shivering

Timepoint
Every 15 minutes from the beginning of the operation until the end of recovery

Method of measurement
Using Mahajan and Grassi criteria

2

Description
Central temprature

Timepoint
Every 15 minutes from the beginning of the operation until the end of recovery

Method of measurement
Tympanic thermometer

3

Description
Peripheral Temprature

Timepoint
Every 15 minutes from the beginning of the operation until the end of recovery
Method of measurement
Skin thermometer

Secondary outcomes

1

Description
Systolic Blood Pressure
Timepoint
Every 15 minutes from the beginning of the spinal anesthesia to the end of recovery
Method of measurement
Non invasive blood pressure measurement

2

Description
Diastolic Blood Pressure
Timepoint
Every 15 minutes from the beginning of the spinal anesthesia to the end of recovery
Method of measurement
Non invasive blood pressure measurement

3

Description
Mean Arterial Blood Pressure
Timepoint
Every 15 minutes from the beginning of the spinal anesthesia to the end of recovery
Method of measurement
Non invasive blood pressure measurement

4

Description
Heart Rate
Timepoint
From the beginning of the spinal anesthesia to the end of recovery
Method of measurement
Heart monitoring device

5

Description
Oxygen saturation
Timepoint
From the beginning of the spinal anesthesia to the end of recovery
Method of measurement
Pulse oximetry device

Intervention groups

1

Description
Intervention group A: Ondansetron is injected into the patient at a dose of 4 mg immediately after umbilical cord clamping.
Category
Treatment - Drugs

2

Description
Intervention Group A; Ketamine 0.5 mg per kilogram of body weight is injected into the patient immediately after clamping the umbilical cord.
Category
Treatment - Drugs

3

Description
Control group C: Normal saline as a placebo is injected into the patient immediately after the umbilical cord clamp.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan 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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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