

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 Ondansetron 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

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

Isfahan

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

Name of organization / entity

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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
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Shirini
Position
Medical student
Latest degree
Medical doctor
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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