

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between prophylactic low dose ketamine and ondansetron for prevention of shivering after spinal anesthesia for elective cesarean section

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is Comparison between prophylactic low dose ketamine and ondansetron for prevention of shivering after spinal anesthesia for elective cesarean section. Total of sample size is 117 patient with ages: 18-40 years old. Inclusion criteria are patients candidate for elective cesarean section with pfannenstiell incision, under spinal anesthesia. The patients with With a history of cardiovascular disease, allergy to ketamine or ondansetron will be excluded. Patients are randomly divided into three groups with table of random numbers by computer. Assessor of study and patients do not know about type of drug and grouping people. This study is 2-3 trial phase. First group receives 0.25 mg/kg of ketamin diluted in 10 ml normal saline, intravenously after spinal anesthesia. Second group receives 4 mg of ondansetron diluted in 10 ml of normal saline, intravenously after spinal anesthesia. Third group receives 10 ml of normal saline, intravenously after spinal anesthesia. Patients basic information such as age and sex, BMI, systolic and diastolic blood pressure, heart rate, intensity of patients shivering, dizziness, allergic reactions, nausea, vomiting and hallucinations during surgery and after surgery will be recorded in all three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040627258N1**

Registration date: **2016-05-14, 1395/02/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-14, 1395/02/25

Registrant information

Name

Nazli Arbabi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 2922

Email address

arbabi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between prophylactic low dose ketamine and ondansetron for prevention of shivering after spinal anesthesia for elective cesarean section

Public title

The effect of ketamine and ondansetron for prevention of shivering after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patients candidate for elective cesarean section with pfannenstiell incision under spinal anesthesia; ASA (American society of anesthesiology) physical class one and two; Patient with ages: 18-40 years old. Exclusion Criteria: history of kidney problems; cardiovascular disease; liver disease; mental illness; seizures; glaucoma; receiving blood products during surgery; lack of patient satisfaction; allergy to ketamine and ondansetron.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **117**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

IR.AJUMS.REC.1394.498

Health conditions studied

1

Description of health condition studied

shivering during and after spinal anesthesia

ICD-10 code

R68.0

ICD-10 code description

Hypothermia, not associated with low environmental temperature

Primary outcomes

1

Description

Intensity of shivering patients

Timepoint

Every 10 minute to 1 hour after surgery

Method of measurement

Based on the score shivering (0-4)

2

Description

Systolic blood pressure and diastolic blood pressure

Timepoint

Before administration and every ten minutes to an hour after surgery

Method of measurement

By using the pressure gauge - in millimeters of mercury

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Prescription 0.25 mg/kg of ketamin diluted in 10 ml normal saline, intravenously after spinal anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group 2: Prescription 4 mg of ondansetron diluted in 10 ml of normal saline, intravenously after spinal anesthesia.

Category

Treatment - Drugs

3

Description

Control group: Prescription 10 ml of normal saline, intravenously after spinal anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khomeini Hospital

Full name of responsible person

Mohammad Reza Gusheh

Street address

Khomeini Hospital, Shahid Ahvazian St., Ahvaz

City

Ahvaz

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
GolestanBLvd., Ahvaz

City

Ahvaz

Postal code**Phone**

+98 61 3222 2922

Fax**Email**

nazli_arbabi@yahoo.com

Web page address

-

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor For Research Of Ahvaz Jondishapour
University of Medical Sciences, Ground Floor, Central
Library, Ahvaz Jundishapur University of Medical
Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor For Research Of Ahvaz Jundishapur
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nazli Arbabi

Position

Resident of anesthesiology

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ahmad Reza Mohtadi

Position

anesthesiologist

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

-

Phone

+98 61 3222 2922

Fax

-

Email

mohtadi.ar@yahoo.com

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sanaz Nazari

Position

Nurse Anesthesia

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

-

Phone

00

Fax

Email

s.nz1990@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty