

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of low dose Ketamine versus placebo on post-operative pain after cesarean section under spinal anesthesia: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of low dose Ketamine versus placebo on post-operative pain after cesarean section under spinal anesthesia

##### Design

This is a double-blind randomized clinical trial, phase III, in which 84 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible women candidate for elective cesarean section referring to the Fatemeh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients or data analyzer will be aware of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years; Candidate for elective cesarean section; Gestational age of 36 to 40 weeks; Exclusion criteria: History of cardiac disease; Hypersensitivity to Ketamine; Renal or liver disease; Hypertension or hyperthyroidism; History of convulsion; Alcohol or drug abuse; Contraindication of spinal anesthesia; Psychological disease

##### Intervention groups

Intervention group: Intravenous Midazolam 1 mg plus Ketamine (manufactured by Opterop pharmaceutical Co.) 0.5 mg/kg single dose before cesarean section Control group: Intravenous Midazolam 1 mg plus normal saline (manufactured by Samen pharmaceutical Co.) 3 ml single dose before cesarean section

##### Main outcome variables

Primary outcome: Pain severity Secondary outcome: Nausea and vomiting, vertigo, hypotension

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N406**

Registration date: **2021-11-04, 1400/08/13**

Registration timing: **prospective**

Last update: **2021-11-04, 1400/08/13**

Update count: **0**

##### Registration date

2021-11-04, 1400/08/13

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of low dose Ketamine versus placebo on post-operative pain after cesarean section under spinal anesthesia: a double-blind randomized clinical trial

**Public title**

Effect of low dose Ketamine versus placebo on post-operative pain after cesarean section under spinal anesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 35 years; Candidate for elective cesarean section; Gestational age of 36 to 40 weeks;

**Exclusion criteria:**

History of cardiac disease; Hypersensitivity to Ketamine; Renal or liver disease; Hypertension or hyperthyroidism; History of convulsion; Alcohol or drug abuse; Contraindication of spinal anesthesia; Psychological disease

**Age**

From **13 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The appearance of the medication (Ketamine) and placebo will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as double-blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2021-10-16, 1400/07/24

**Ethics committee reference number**

IR.UMSHA.REC.1400.557

**Health conditions studied****1****Description of health condition studied**

Pain of cesarean delivery wound

**ICD-10 code**

O90.0

**ICD-10 code description**

Disruption of cesarean delivery wound

**Primary outcomes****1****Description**

Pain severity

**Timepoint**

On 2, 4, and 6 hours after cesarean section

**Method of measurement**

Using Visual Analog Scale (VAS)

**Secondary outcomes****1****Description**

Nausea and vomiting

**Timepoint**

On 2, 4, and 6 hours after cesarean section

**Method of measurement**

Via taking history

## 2

### **Description**

Vertigo

### **Timepoint**

On 2, 4, and 6 hours after cesarean section

### **Method of measurement**

Via taking history

## 3

### **Description**

Hypotension

### **Timepoint**

On 2, 4, and 6 hours after cesarean section

### **Method of measurement**

Via physical examination by sphygmometer

## **Intervention groups**

### 1

#### **Description**

Intervention group: Intravenous Midazolam 1 mg plus Ketamine (manufactured by Opterop pharmaceutical Co.) 0.5 mg/kg single dose before cesarean section

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Intravenous Midazolam 1 mg plus normal saline (manufactured by Samen pharmaceutical Co.) 3 ml single dose before cesarean section

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Fatemieh Hospital in Hamadan city

##### **Full name of responsible person**

Azadeh Fasihi

##### **Street address**

Fatemieh Hospital, Pasdaran Ave.

##### **City**

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##### **Postal code**

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##### **Phone**

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##### **Email**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Hamedan University of Medical Sciences

##### **Full name of responsible person**

Dr. Saeid Bashirian

##### **Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

##### **Full name of responsible person**

Azadeh Fasihi

##### **Position**

Medical Student

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Davoudi

**Position**

Anesthesiologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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