

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Analgesic effects of subcutaneous of low dose Ketamine before and after cesarean section surgery**

#### **Protocol summary**

##### **Summary**

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a double-blind prospective, randomized study will be done among patients with Elective Cesarean Section. Spinal anesthesia with 12.5 mg Marcaine will done in both groups equally. Inclusion criteria: - The patient's satisfaction - Age between 20 and 40 years old - ASA class I & II Exclusion criteria: - The lack of patient's satisfaction to spinal anesthesia - History of hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol- dependency - Contraindication of Ketamine - Contraindications of Spinal Anesthesia( Patient refusal ; Infection at the site of planned needle puncture ; Elevated intracranial pressure and Bleeding diathesis) Patients will be randomly allocated into three groups according to table of random numbers. Groups "one", "two", and "three" will receive 0.5 mg/kg of ketamine with 10 ml Normal Saline Before surgery incision in place of incision Subcutaneously, 0.5 mg/kg of ketamine with 10 ml Normal Saline after end of surgery in place of incision Subcutaneously, and 10 ml Normal Saline after end of surgery in place of incision Subcutaneously, respectively. Postoperative pain and needs for analgesics will measured at 1,2,4,6,12,18 and 24 hours after surgery.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2013022012539N1**  
Registration date: **2013-08-17, 1392/05/26**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### **Registration date**

2013-08-17, 1392/05/26

##### **Registrant information**

###### **Name**

Mehdi Aslani

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

Ahvaz Jundishapur University of Medical Sciences

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 61 1222 0198

###### **Email address**

aslani.m@ajums.ac.ir

##### **Recruitment status**

###### **Recruitment complete**

##### **Funding source**

Vice chancellor for research, Ahvaz University of Medical Sciences

##### **Expected recruitment start date**

2013-09-23, 1392/07/01

##### **Expected recruitment end date**

2014-01-21, 1392/11/01

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

Analgesic effects of subcutaneous of low dose Ketamine before and after cesarean section surgery

##### **Public title**

Analgesic effects of subcutaneous of low dose Ketamine before and after cesarean section surgery

##### **Purpose**

Prevention

##### **Inclusion/Exclusion criteria**

Inclusion criteria: - The patient's satisfaction - Age between 20 and 40 years old - ASA class I & II Exclusion criteria: - The lack of patient's satisfaction to spinal anesthesia - History of hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol-dependency - Contraindication of Ketamine - Contraindications of Spinal Anesthesia( Patient refusal ; Infection at the site of planned needle puncture ; Elevated intracranial pressure and Bleeding diathesis)

#### Age

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

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### 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

No.12, Chamber Sadaf, Golestan Blvd

##### City

Ahvaz

##### Postal code

6135733777

#### Approval date

2012-12-19, 1391/09/29

#### Ethics committee reference number

ETH-641

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

R52.0

#### ICD-10 code description

Acute Pain

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

1,2,4,6,12,18 and 24 hours after surgery

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Opioid Consumption

#### Timepoint

24 hours after surgery

#### Method of measurement

Milligram

## Intervention groups

### 1

#### Description

Drugs: 1-Ketamine: Dose: 0.5mg/kg Number of using: Once Factory name: Rotex medica Manufacturing Country's Name: Germany Location prescribed: In place of incision Subcutaneously Administration time: Before surgery incision 2- Normal Saline: Dose: 10 ml Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: In place of incision Subcutaneously Administration time: Before surgery incision

#### Category

Treatment - Drugs

### 2

#### Description

Drugs: 1-Ketamine: Dose: 0.5mg/kg Number of using: Once Factory name: Rotex medica Manufacturing Country's Name: Germany Location prescribed: In place of incision Subcutaneously Administration time: After end of surgery 2- Normal Saline: Dose: 10 ml Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: In place of incision Subcutaneously Administration time: After end of surgery

#### Category

Treatment - Drugs

### 3

#### Description

Drug: Normal Saline Dose: 10 ml Number of using: Once

Factory name: Daroupakhsh Manufacturing Country's  
Name: Iran Location prescribed: In place of incision  
Subcutaneously Administration time: After end of surgery

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Educational Hospital

**Full name of responsible person**

Dr. Kaveh Behaeen

**Street address**

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

**City**

Ahvaz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Ahvaz Jundishapur  
University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Feghhi

**Street address**

No. 21, Ave. 1, Golestan Blvd.

**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, 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**

Mehdi Aslani

**Position**

Resident of Anesthesia

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**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*