

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of intravenous injection of midazolam ,midazolam- ketamine and ketamine on reduce prevalence of post spinal shivering in patients undergoing elective cesarean section

#### Protocol summary

##### Summary

The overall goal: to determine the prevalence of shivering after spinal anesthesia for caesarean section in groups of midazolam, midazolam - ketamine and ketamine. Study design: Randomized, single-blind, placebo-controlled. The study population: consists of patients who were referred for elective cesarean section Fatemeh Hospital operating room in Hamadan City Inclusion criteria: (a) Age 18-40 years and undergoing cesarean section; (b) ; physical status class I or II in accordance with anesthesia; (c) Term pregnancy (gestational age 36-40 weeks); (d) Singleton pregnancy. Exclusion criteria: (a) High-risk pregnancy; (b) Preeclampsia;(c) A history of cardiovascular disease, lung disease, mental, thyroid disease, diabetes mellitus type 1 and 2;(d) needs to blood or blood supply transfusion;(e) Fever over 38 ° C;(f) Drag over an hour during surgery;(g) A history of nausea and vomiting to Previous surgery;(h) Patients with spinal anesthesia ban. The sample size:In this study, 31 patients in each group is examined. Intervention or interventions studied: Patients were randomly divided into four groups A Midazolam75 µg / kg, Group B ketamine 0/5mg / kg, Group C ketamine0/25 mg / kg + 37/5µg / kg midazolam and Group D (control group) received normal saline 9/0% divided. Drugs after clamping the umbilical cord is injected intravenously. Shivering will be evaluated by crosly scale and sedation score will be evaluated by Ramsay sedation scale. Primary outcome or outcomes studied: Side effects such as nausea and vomiting after surgery, Changes in blood pressure and heart rate, arterial oxygen saturation and hallucination will be reviewed and evaluated at the end of the above parameters.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016043012251N3**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-05-21, 1395/03/01

##### Registrant information

##### Name

Nasim Alipour

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 918 312 6716

##### Email address

n.alipour@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2016-10-22, 1395/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of intravenous injection of midazolam ,midazolam- ketamine and ketamine on reduce prevalence of post spinal shivering in patients undergoing elective cesarean section

**Public title**

The effect of intravenous injection of midazolam ,midazolam- ketamine and ketamine on reduce prevalence of post spinal shivering

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: (a) Age 18-40 years and undergoing cesarean section; (b) ; physical status class I or II in accordance with anesthesia; (c) Term pregnancy (gestational age 36-40 weeks); (d) Singleton pregnancy. Exclusion criteria: (a) High-risk pregnancy; (b) Preeclampsia;(c) A history of cardiovascular disease, lung disease, mental, thyroid disease, diabetes mellitus type 1 and 2;(d) needs to blood or blood supply transfusion;(e) Fever over 38 ° C;(f) Drag over an hour during surgery;(g) A history of nausea and vomiting to Previous surgery;(h) Despite the decrease in body temperature or shivering before the start of anesthesia due to fear or other reasons;(i) Patients with spinal anesthesia ban.

**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: **124**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

Research Ethics Committee of Hamadan University of Medical Sciences

**Street address**

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

**City**

Hamadan

**Postal code**

6517838695

**Approval date**

2016-04-09, 1395/01/21

**Ethics committee reference number**

IR.UMSHA.REC.1395.2

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

post spinal shivering

**ICD-10 code**

T88.5

**ICD-10 code description**

Other complications of anaesthesia

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

Shivering after spinal anesthesia in patients undergoing elective cesarean

**Timepoint**

Since spinal anesthesia or intravenous of midazolam, ketamine ,midazolam- ketamine or normal saline

**Method of measurement**

Shivering intensity divided by 4 score will be assessed. Grade zero: no Shivering . Grade1: mild fasciculation in the face and neck. Grade2: trembling visible muscle groups in more than one category. Grade 3: Zlany activity of the whole body is involved.

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

heart rate

**Timepoint**

during the surgery and recovery

**Method of measurement**

Cardiac monitor

**2****Description**

arterial blood oxygen saturation

**Timepoint**

during the surgery and recovery

**Method of measurement**

Pulse oximeter

### 3

**Description**

Hemodynamic instability

**Timepoint**

during the surgery and recovery

**Method of measurement**

Sphygmomanometer

### 4

**Description**

hallucination

**Timepoint**

during the surgery and recovery

**Method of measurement**

Observation

### 5

**Description**

Sedation Score

**Timepoint**

during the surgery and recovery

**Method of measurement**

Ramsay score

## Intervention groups

### 1

**Description**

In First group, we will inject 75 µg /kg of Midazolam IV. after clamping the umbilical cord.

**Category**

Prevention

### 2

**Description**

In Second group, we will inject 0/5mg / kg of ketamine IV. after clamping the umbilical cord.

**Category**

Prevention

### 3

**Description**

In Third group, we will inject 0/25mg / kg of ketamine and 37/5µg / kg midazolam IV. after clamping the umbilical cord.

**Category**

Prevention

### 4

**Description**

In control group we will inject 2 cc of Normal saline 0/9% IV. after clamping the umbilical cord

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Fatemieh Hospital

**Full name of responsible person**

Nasim Alipour

**Street address****City**

Hamadan

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**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 the Technology, Hamadan 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**

Fatemieh Hospital

**Full name of responsible person**

Nasim Alipour

**Position**

Master of Critical Care Nurses, Clinical instructor

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

Fatemieh hospital, Pasdaran Ave.

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n.alipour@umsha.ac.ir  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Fatemieh Hospital  
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Dr. Nahid Manouchehrian  
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Associated professor of Anesthesia Department  
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## Person responsible for updating data

### Contact

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**Position**  
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## 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*