

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)

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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

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

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

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Person responsible for scientific inquiries

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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