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 Fatemieh 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)

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+98 81 1838 0090

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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.
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6517838695
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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
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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
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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Position
Anesthesiologist

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Professor of Epidemiology

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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