Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effect of ketamine with gabapentin on the severity of some complications of spinal anesthesia in cesarean section

Protocol summary

Study aim
1. Determining and comparing the severity of headache, nausea, vomiting and level of mother's satisfaction in intervention groups (ketamine, vegabapentin, ketamine, gabapentin) and control (placebo)

Design
A single-blind clinical trial with a control group and three intervention groups, with parallel groups, randomized by simple randomization method, phase 3 on 120 patients.

Settings and conduct
The current study is on the treatment of cesarean complications in the field of obstetrics and gynecology, which will be conducted at Yasouj University of Medical Sciences. Patients will be randomly divided into four groups. The study is single blinded. The patients doesn't informed about the medicine. During the study and at the end of the study, the variables will be checked.

Participants/Inclusion and exclusion criteria
Age between 18 and 34 years, Husband and patient's consent to participate in the study, Gestational age greater than or equal to 28 weeks, Absence of underlying disease or medication use that prevents the procedure.

Intervention groups
Group A: They receive gabapentin (single oral dose, 300 mg) 30 minutes before surgery. Group B: ketamine (intravenous dose of 0.25mg/kg as a single bolus dose) five minutes after cord clamping. Group C: simultaneous administration of ketamine (intravenous dose of 0.25 mg/kg as a single bolus dose) along with gabapentin (single oral dose, 300 mg) Group D: receiving placebo (intravenous distilled water)

Main outcome variables
Severe nausea and vomiting after surgery Severity of headache after surgery Patient satisfaction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230316057741N1**
Registration date: **2023-04-09, 1402/01/20**
Registration timing: **prospective**

Last update: **2023-04-09, 1402/01/20**
Update count: **0**

Registration date
2023-04-09, 1402/01/20

Registrant information

Name
Zahra Asadi Kalemeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-20, 1402/02/30

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of ketamine with gabapentin on the severity of some complications of spinal anesthesia in cesarean section

Public title
The effect of ketamine along with gabapentin on complications of spinal anesthesia in caesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
No emergency C/S surgery No emergency C/S surgery No emergency C/S surgery Type of surgical incision on the skin of Von Stilweber on the uterus, transverse incision on the lower uterine segment (kerr) Absence of underlying disease such as weak immune system, diabetes, high blood pressure, cardiopulmonary disease, blood disease, autoimmune disease, severe liver hepatitis, asthma, pancreatitis, or coagulation disorders. Singleton pregnancy Not taking special medicine Gestational age greater than or equal to 28 weeks Being in the low risk group based on the risk factors of PPH, including placenta previa, placental abruption, hypertension, HELLP syndrome, macrosomia, non-cephalic presentation, intrauterine infection or the use of assisted reproductive technology (ART). Mother's BMI based on pre-pregnancy weight less than 30 kg/m2 Natural plt counting
Exclusion criteria:
Any contraindications for spinal anesthesia Any contraindications to receiving ketamine or gabapentin Severe bleeding during C/S If any of the patients in the placebo group suffer from any of the side effects that cannot be tolerated by the patient, the patient will be treated for the side effects with the opinion of the relevant specialist, and the patient will be excluded from the study.
Age
From **18 years** old to **34 years** old
Gender
Female

Phase
3
Groups that have been masked

- Care provider

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, eligible patients are randomly divided into four groups. Randomization will be simple and individual. The names of each patient will be written as a number on a piece of paper and will be placed inside the appropriate envelopes, four people will randomly remove them from the envelopes and each will enter one of the four groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Care provider will not informed about the type of intervention received by patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yasouj University of Medical Sciences
Street address
Yasouj University of Medical Sciences, MHHQ+493, Shahid Motahari Blvd, Kohgiluyeh and Boyer-Ahmad Province, Yasuj
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Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2023-02-15, 1401/11/26
Ethics committee reference number
IR.YUMS.REC.1401.178

Health conditions studied

1

Description of health condition studied
Complications after cesarean section
ICD-10 code
Z38.01
ICD-10 code description
Single liveborn infant, delivered by cesarean

Primary outcomes

1

Description
Severity of postoperative nausea and vomiting
Timepoint
Their nausea and vomiting at intervals of 1, 2, 3, 4 and 6 hours
Method of measurement
A Visual Analogue Scale will be used to measure the severity of nausea and vomiting after the operation

2

Description
severity of postoperative headache
Timepoint
Headache at intervals of 1, 6, 12 hours after the operation

Method of measurement
A Visual Analogue Scale will be used to measure the severity of headache

3

Description
Postoperative patient satisfaction score
Timepoint
Post-operation
Method of measurement
A Visual Analogue Scale will be used to measure the patient satisfaction

Secondary outcomes

empty

Intervention groups

1

Description
Intervention first group: Receive gabapentin (single oral dose, 300 mg) 30 minutes before surgery.
Category
Prevention

2

Description
Intervention second group: Ketamine (intravenous dose of 0.25mg/kg as a single bolus dose) five minutes after cord clamping.
Category
Prevention

3

Description
Intervention third group: Ŝimultaneous administration of ketamine (intravenous dose of 0.25 mg/kg as a single bolus dose) along with gabapentin (single oral dose, 300 mg)
Category
Prevention

4

Description
Control group: Receiving placebo (intravenous distilled water)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Hospital
Full name of responsible person
Zahra Asadi Kalemeh
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Imam Sajjad Hospital St, Azadi Bagheri St., Yasouj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Street address
International Affairs Office, Central Library, Yasuj University of Medical Sciences, Shahid Dr. Jalil St., Yasuj, Kohgilouyeh and Boyer-Ahmad Province, Iran.
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Web page address
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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
Yasouj 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
Yasouj University of Medical Sciences

Full name of responsible person
Zahra Asadi Kalemeh

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
The intended data that is the result of this study and can be published includes the results of the study and the data of participants without names and identity information after the study is conducted and if necessary after the publication of the article from this study with the person responsible and responsible for the project. It can be shared if you contact them.

When the data will become available and for how long
The access period starts 3 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data obtained from this study is only allowed for

further study and further analysis is also allowed for review studies and meta-analysis and otherwise it will not be available for other matters.

From where data/document is obtainable

zasadik66@gmail.com

What processes are involved for a request to access data/document

Eligible people to receive documents must send a written and signed letter from the scientific institute or the scientific board of one of the universities to the given email address.

Comments