

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)

Phone

+98 74 3222 0163

Email address

zasadik66@gmail.com

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-Boyerahmad

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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: Simultaneous 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

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International Affairs Office, Central Library, Yasouj University of Medical Sciences, Shahid Dr. Jalil St., Yasouj, Kohgilouyeh and Boyer-Ahmad Province, Iran.

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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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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