

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Investigation of the prophylactic effect of intravenous ketamine on the amount of bleeding and intravenous oxytocin consumption in elective cesarean section

Protocol summary

Study aim

The effect of intravenous ketamine on bleeding and intravenous oxytocin usage during elective cesarean section

Design

A double-blinded and randomized clinical trial with a control group and parallel groups design of 210 patients

Settings and conduct

This study is performed as a clinical trial in Al-Zahra Hospital in Rasht. Eligible patients first receive sufficient explanations, then informed consent will be obtained. Initially, by convenience sampling, pregnant women who are candidates for elective cesarean section by regional anesthesia method will be selected. They will be divided into two groups of ketamine and control using block size of 4. Drugs will be prepared by a trained anesthesia technician in exactly the same syringes and provided to the anesthesiologist. In both groups, oxytocin is prescribed after childbirth. Immediately after the umbilical cord clamp. In the intervention group, ketamine, and in the control group, normal saline will be administered. The number of oxytocin units consumed, amount of bleeding, and possible complications will be recorded in both groups. In this study, patients and evaluator are blind. The evaluation will be performed by the responsible anesthesia assistant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women candidates for elective cesarean section, Regional anesthesia method
Exclusion criteria: allergic to ketamine, history of seizure or psychological illnesses

Intervention groups

Intervention group: 0.25 milligrams per kilogram of intravenous ketamine (Ampule 500 milligram in 10 milliliters, manufacturer: Sterop, country: Belgium) will be administered immediately after the umbilical cord clamp. control group: 2 milliliters of normal saline will be

administered immediately after the umbilical cord clamp.

Main outcome variables

Bleeding rate, oxytocin consumption, complications (hallucination, nausea, vomiting)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170314033069N3**
Registration date: **2020-12-31, 1399/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-31, 1399/10/11**

Update count: **0**

Registration date

2020-12-31, 1399/10/11

Registrant information

Name

Gelare Bazar Bazar

Name of organization / entity

Guilan University of Medical Sciences, Alzahra Hospital

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9024

Email address

biazar@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-22, 1400/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Investigation of the prophylactic effect of intravenous ketamine on the amount of bleeding and intravenous oxytocin consumption in elective cesarean section

Public title
The effect of ketamine on bleeding and oxytocin consumption during cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women candidates for elective cesarean section Regional anesthesia method
Exclusion criteria:
Reluctant to participate in the project allergic to ketamine history of seizures history of psychological illnesses

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **210**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of initial selection of individuals to enter the project will be in the form of convenience sampling of pregnant women who are candidates for elective cesarean section by regional anesthesia method. Eligible patients will be divided into two groups of ketamine and normal saline (control) using block size of 4, created by the computer and WinPepi Ver.11.65 software which is prepared by the methodology consultant.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patient and the evaluator are unaware of the treatment groups. The evaluation will be performed by an anesthesia assistant. drugs include ketamine and normal saline will be prepared by a trained anesthesia technician who is not in the study, in exactly the same syringes, and from a list of eligible patients, one by one from each group using a random list. After that it will be given to the anesthesia assistant. Drugs will be injected to the patients of both groups, Immediately after the umbilical cord clamp. The number of oxytocin

units, primary outcomes (bleeding rate based on changes in hemoglobin levels) before and after surgery as well as secondary outcomes (complications such as nausea, vomiting, hallucinations) during surgery and in recovery will be recorded by the anesthesia assistant.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

City

Rasht

Province

Guilan

Postal code

4144654839

Approval date

2020-11-25, 1399/09/05

Ethics committee reference number

IR.GUMS.REC.1399.385

Health conditions studied

1

Description of health condition studied

Maternal care to reduce bleeding during cesarean section

ICD-10 code

O26

ICD-10 code description

Maternal care for other conditions predominantly related to pregnancy

Primary outcomes

1

Description

Bleeding rate

Timepoint

Before and after surgery

Method of measurement

Based on changes in hemoglobin levels

2

Description

Oxytocin consumption

Timepoint

At the end of surgery

Method of measurement

Units per minute

Secondary outcomes

1

Description

Complications(nausea, vomiting and hallucination)

Timepoint

During operation and in recovery

Method of measurement

observation

Intervention groups

1

Description

Intervention group: Eligible patients first receive adequate explanations of this research and then informed consent is obtained. After the baby's birth, oxytocin will be given at a rate of 0.4 units per minute. Then immediately after the umbilical cord clamp, 0.25 milligrams per kilogram of intravenous ketamine (Ampule 500 milligram in 10 milliliters, manufacturer: Sterop, country: Belgium) will be prescribed.

Category

Treatment - Drugs

2

Description

Control group: Eligible patients first receive adequate explanations of this research and then informed consent is obtained. After the baby's birth, oxytocin will be given at a rate of 0.4 units per minute. Then immediately after the umbilical cord clamp, 2 milliliters of intravenous normal saline will be prescribed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr Gelareh Biazar

Street address

Alzahra Hospital, Shahid Siadati Avenue, Namjoo Street, Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research Guilan university of medical sciences

Full name of responsible person

Dr Mohammadreza Naghipoor

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

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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 President of Research Guilan 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

Anesthesiology Research Center

Full name of responsible person

Dr Gelareh Biazar

Position

associate professor, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

associate professor, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Position

Research Expert/(MSc) English

Latest degree

Master

Other areas of specialty/work

Research Expert

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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