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 Biazar Biazar

Name of organization / entity
Guilan University of Medical Sciences,Alzahra Hospital

Country
Iran (Islamic Republic of)

Phone
+98 13 3336 9024

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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
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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
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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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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