Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Investigating the effect of intravenous lidocaine on awareness during elective cesarean section under general anesthesia

Protocol summary

Study aim
Determining the effect of intravenous lidocaine on awareness during general anesthesia in elective cesarean section

Design
A double-blinded and randomized clinical trial with parallel groups design of 52 patients.

Settings and conduct
This study is conducted as a clinical trial in Alzahra Hospital in Rasht. After explaining the purpose and method of the research, informed consent will be obtained. Immediately after entering the operating room, patients will undergo non-invasive monitoring of blood pressure, heart rate and pulse oximetry. The general principles of anesthesia will be the same for both groups. Drugs will be prepared in similar syringes by an anesthetist technician who is not aware of the goals of the study. This study is double-blind. Patients and the evaluator (trained medical student) who conducts the interview are unaware of the treatment groups. The anesthetist technician present in the operating room is aware of the groups in order to provide necessary information to the anesthesiologist to perform the necessary intervention in case of complications.

Participants/Inclusion and exclusion criteria
Inclusion criteria: pregnant women candidates for cesarean section under general anesthesia, hemodynamically stable condition. Exclusion criteria: inability to communicate verbally appropriately, sensitivity to local amide anesthetics.

Intervention groups
In the lidocaine group, before induction of anesthesia, 1 milligram per kilogram of intravenous lidocaine 2% (100 milligram/5 milliliters, Aburaihan Pharmaceutical Company, Iran) will be injected. In the placebo group, the same volume (1 milligram per kilogram) of normal saline will be injected.

Main outcome variables
The effectiveness of lidocaine on the frequency of different states of the first memory after regaining consciousness, the last memory before anesthesia and awareness during anesthesia.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170314033069N7**
Registration date: **2023-09-12, 1402/06/21**
Registration timing: **prospective**

Last update: **2023-09-12, 1402/06/21**
Update count: **0**

Registration date
2023-09-12, 1402/06/21

Registrant information

Name
Gelare Biazar Biazar

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

Country
Iran (Islamic Republic of)

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biazar@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2025-03-20, 1403/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of intravenous lidocaine on awareness during elective cesarean section under general anesthesia

Public title
The effect of lidocaine on wakefulness during general anesthesia in elective cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women candidates for caesarean section surgery under general anesthesia American Society of Anesthesiologists (ASA) II, I Hemodynamically stable condition
Exclusion criteria:
Inability to communicate appropriately verbally to fill out the questionnaire sensitivity to local amide acetic acid Any contraindications to the use of ondansetron (heart problems, especially Long Q-T) Contraindications to Apotel (liver failure) Contraindications to propofol (including drug-food allergies) Contraindications to lidocaine, including heart blocks (bradydysrhythmias) The presence of any psychiatric disorder that interferes with answering the questions. A history of malignant hyperthermia that prohibits the use of inhaled gases and succinylcholine.
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized by a random sequence created in blocks of four by computer (Win Pepi 11.65 software). An anesthesiologist who has not participated in the project, through the list of eligible patients who gave informed consent and the sequence of randomization blocks in a ratio of 1:1 will assign patients to one of the two groups of lidocaine or placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double-blind. The patient and the evaluator (trained medical student) who conducts the interview are unaware of the treatment groups. The drugs will be prepared in similar syringes by the anesthetist technician, who is not aware of the plan's goals and will be provided to the anesthesiologist so that the difference between the two cannot be identified. The responsible anesthetist technician present in the operating room is aware of the groups so that in case of complications, he will provide the necessary information for the anesthesiologist to perform the necessary intervention.
Placebo
Not 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
2023-08-23, 1402/06/01
Ethics committee reference number
IR.GUMS.REC.1402.311

Health conditions studied

1

Description of health condition studied
Effect of intravenous lidocaine on awareness during general anesthesia for elective cesarean section
ICD-10 code
R41.8
ICD-10 code description
Other symptoms and signs involving cognitive functions and awareness

Primary outcomes

1

Description
The effectiveness of lidocaine on the frequency of different states of the first memory after regaining consciousness
Timepoint
24 hours after surgery

Method of measurement
Face-to-face interview

2

Description
The effectiveness of lidocaine on the frequency of different states of the last memory before anesthesia of patients
Timepoint
24 hours after surgery
Method of measurement
Face-to-face interview

3

Description
The effectiveness of lidocaine on the frequency of different conditions related to awareness during anesthesia
Timepoint
24 hours after surgery
Method of measurement
Face-to-face interview

Secondary outcomes

1

Description
The effect of lidocaine on hemodynamic changes of patients (mean blood pressure and heart rate of the patient)
Timepoint
4 stations: base time (before injection of lidocaine), after intubation, end of operation, and after extubation
Method of measurement
Blood pressure and heart rate monitoring of patients

Intervention groups

1

Description
Intervention group: In the lidocaine group, before induction of anesthesia, 1 milligram per kilogram intravenous lidocaine 2% (100 milligram/5 milliliter, Aburaihan Pharmaceutical Company, Iran) will be injected.
Category
Treatment - Drugs

2

Description
Control group: In the placebo group, the same volume (1 milligram per kilogram) of normal saline will be injected.
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
Rasht University of Medical Sciences
Full name of responsible person
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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
Rasht 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
Rasht University of Medical Sciences

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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Research Expert/(MSc) English

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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