

# 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)

##### Phone

+98 13 3336 9024

##### Email address

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

##### City

Rasht

##### Province

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##### Postal code

4144654839

##### Phone

+98 13 3332 9524

##### Email

alzahra@gums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht 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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##### Province

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naghi@gums.ac.ir

#### 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

+98 13 3332 9524

## Person responsible for general inquiries

### Fax

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### Email

gelarehbiazar1386@gmail.com

### Web page address

### 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

#### Street address

Anesthesiology Research Center, Alzahra Hospital,  
Namjoo Street, Rasht, Iran

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## Person responsible for updating data

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Mohadese Ahmadi

#### Position

Research Expert/(MSc) English

#### Latest degree

Master

#### Other areas of specialty/work

Research Expert

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## Person responsible for scientific 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

#### Street address

Anesthesiology Research Center, Alzahra Hospital,  
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#### City

Rasht

#### Province

Guilan

#### Postal code

4144654839

#### Phone

## 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