

# The impact of administering lidocaine intravenously prior to removing the breathing tube on recovery following breast surgery

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
02/07/2023	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
04/07/2023	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
04/07/2023	Surgery	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aim

Breast surgery is a common procedure with potential postoperative complications such as pain, nausea, and delayed recovery. By exploring the use of IV lidocaine during surgery, we can potentially alleviate these issues and enhance the overall recovery experience.

Lidocaine is commonly used as a local anesthetic, however, its benefits in the context of general anesthesia and postoperative recovery are still being studied. Focusing on women undergoing breast surgery allows us to specifically evaluate the effects of IV lidocaine in this patient population.

Understanding the impact of IV lidocaine on emergence, early recovery, and late recovery after breast surgery can lead to improved patient outcomes and satisfaction. Positive results from the study may encourage healthcare providers to incorporate lidocaine administration into anesthesia protocols for breast surgery, potentially reducing postoperative pain, shortening recovery times, and enhancing overall patient well-being.

We aimed to investigate whether IV lidocaine improves emergence, early, and late recovery after general anesthesia in women who undergo breast surgery.

### Who can participate?

Sixty-seven women with American Society of Anesthesiologists physical status I-II, scheduled for breast surgery

### What does the study involve?

All patients received standardized general anesthesia and were randomized to receive IV lidocaine 1.5 mg/kg bolus (n=34) or saline placebo (n=33) before tracheal extubation.

### What are the possible benefits and risks of participating?

IV lidocaine is routinely used at the beginning of anesthesia with minimal complications therefore risks were minimal. The benefit was to participate in the study to enhance medical knowledge.

Where is the study run from?  
Opća Bolnica Zadar (Croatia)

When is the study starting and how long is it expected to run for?  
April 2007 to December 2013

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Tatjana Simurina, tatjana.simurina@zd.htnet.hr

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Tatjana Simurina

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

1280-07

## Study information

### Scientific Title

Effects of intravenous lidocaine bolus before tracheal extubation on recovery after breast surgery – Lidocaine At The End (LATE) study: a randomized controlled clinical trial

### Acronym

LATE study

### **Study objectives**

We investigated whether IV lidocaine would improve emergence and prevent complications in early and late recovery after general anesthesia in women undergoing breast surgery.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 24/05/2007, Ethics Committee, General Hospital Zadar (Boze Pericica 5, Zadar, 23000, Croatia; +385 23505505; opca-bolnica-zadar@zd.t-com.hr), ref: 01-1280/07

### **Study design**

Single-center prospective double-blinded randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention, Treatment

### **Health condition(s) or problem(s) studied**

Quality of the emergence after general anesthesia, prevention of bucking, cough, sore throat, and PONV for 24 hours after general anesthesia in women who underwent breast surgery

### **Interventions**

Patients were randomized by computer-generated random numbers to receive either lidocaine or the same volume of saline (control) on the emergence from anesthesia. At the end of skin closure, volatile anesthetic and N<sub>2</sub>O were switched off, neostigmine 2.5 mg and atropine 1 mg for neuromuscular blockade reversal were given, and the fresh gas inflow rate was increased to 7 L/min of 100% oxygen. At that time, patients received 2% lidocaine IV (1.5 mg/kg) or the same amount of saline (placebo). No physical stimulations were applied during the emergence.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Lidocaine 2% (intravenous)

### **Primary outcome(s)**

Quality of the emergence measured by:

1. The number of bucking episodes before extubation
2. The number of coughs and sore throat episodes at one, three, and five minutes after extubation,
3. The number of coughs and sore throat episodes at two and 24 hours postoperatively

### **Key secondary outcome(s)**

1. PONV - postoperative nausea and vomiting (retching) (incidence, number of episodes)
2. Severity of nausea evaluated with a 100-mm visual analog scale (VAS) (0=no pain to 100=maximum pain) at 2 h and 24h postoperatively
3. Postoperative pain evaluated with a 100-mm visual analog scale (VAS) at the same time points (0=no pain to 100=maximum pain)

**Completion date**

18/12/2013

## Eligibility

**Key inclusion criteria**

1. Adult women
2. American Society of Anesthesiologists physical status I to II
3. Women undergoing breast tumor surgery (lumpectomy, simple mastectomy, radical or modified radical mastectomy)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

Female

**Total final enrolment**

73

**Key exclusion criteria**

1. Anticipated difficult intubation
2. Multiple intubation attempts
3. History of sore throat, cough, and respiratory infections
4. Having been intubated within the last two months
5. Chronic obstructive lung disease
6. Asthma
7. Treatment with  $\beta$ -blocking agents
8. Known hypersensitivity to drugs used in the study protocol
9. Obesity (body mass index  $>30 \text{ kg/m}^2$ )
10. The study protocol was broken
11. Conditions that arose that influenced outcomes during the surgery ( unexpected

intraoperative drug allergy, severe intraoperative hypotension lasting more than three minutes, perioperative hypoxia lasting more than one minute, excessive blood loss, difficult intubation, or serious postoperative surgical complications)

#### **Date of first enrolment**

18/07/2007

#### **Date of final enrolment**

04/12/2013

## **Locations**

#### **Countries of recruitment**

Croatia

#### **Study participating centre**

**General Hospital Zadar**

Boze Pericica 5

Zadar

Croatia

23000

## **Sponsor information**

#### **Organisation**

Opća Bolnica Zadar

#### **ROR**

<https://ror.org/05ds5vg25>

## **Funder(s)**

#### **Funder type**

Other

#### **Funder Name**

Investigator initiated and funded

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The data sets generated and analyzed during the study will be available upon request from Dr. Tatjana Šimurina <[tatjana.simurina@gmail.com](mailto:tatjana.simurina@gmail.com)>

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes