

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

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

ORCID ID

<https://orcid.org/0000-0002-2657-5537>

Contact details

Ul. Bože Peričića 5

Zadar

Croatia

23000

+385 23 505 505

tatjana.simurina@zd.htnet.hr

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention, Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 N2O 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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lidocaine 2% (intravenous)

Primary outcome measure

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

Secondary outcome measures

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)

Overall study start date

01/04/2007

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Female

Target number of participants

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 β -blocking agents
8. Known hypersensitivity to drugs used in the study protocol
9. Obesity (body mass index >30 kg/m²)
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

Sponsor details

Ul. Bože Peričića 5
Zadar
Croatia
23000
+385 23 505 505
opca-bolnica-zadar@zd.t-com.hr

Sponsor type

Hospital/treatment centre

Website

<http://www.bolnica-zadar.hr/>

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/09/2023

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>

IPD sharing plan summary

Available on request