ISRCTN71855856 https://doi.org/10.1186/ISRCTN71855856

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

Registration date
04/07/2023

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
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 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

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 ß-blocking agents
8. Known hypersensitivity to drugs used in the study protocol
9. Obesity (body mass index >30 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>

IPD sharing plan summary

Available on request