Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of lidocaine administration during general anesthesia on inflammatory prognostic scores in breast cancer surgery candidates

Protocol summary

Summary

(1) Objectives: Evaluating the effect of intravenous lidocaine infusion during surgery on inflammatory factor levels based on glasgow prognostic score and neutrophil to lymphocyte ratio in patients candidate for mastectomy due to breast cancer (2) Design: The present study is a double blind randomized clinical trial. All breast cancer patients with ASA: I, II referring to Imam Hosein hospital, Tehran, Iran, who were candidate for elective mastectomy were included. Totally 63 patients were allocated in to 2 groups of intervention (lidocaine) and control (normal saline) based on a random number table. (3) Setting and conduct: General anesthesia was induced similarly for all patients, using midazolam 0.02 mg/kg, fentanyl 2-4 µg/kg, propofol 1-2 mg/kg and atracurium 0.5 mg/kg. (4) Participants: Breast cancer patients candidate for elective mastectomy were included. History of renal or hepatic failure, cardiac dysrhythmia, hospital admission more than 5 days, infection in last 14 days, allergy to lidocaine, recent blood transfusion, blood transfusion during or after surgery, surgery duration more than 4 hours and drug abuse are exclusion criteria. (5) Intervention: In intervention group, 1.5 mg/kg/hr intravenous lidocaine and in control group, the same volume of normal saline was infused intravenously. (6) Main outcome measures: Glasgow prognostic score and neutrophil to lymphocyte ratio were calculated before surgery and 6, 24, 48 hours and 14 days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608029593N5**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name
Elham Memary
Name of organization / entity
Shahid Beheshti University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lidocaine administration during general anesthesia on inflammatory prognostic scores in breast cancer surgery candidates

Public title

The effect of lidocaine administration during general anesthesia on inflammatory prognostic scores in breast

cancer surgery candidates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Breast cancer patients candidate for elective mastectomy;ASA class I, II Exclusion criteria: History of epilepsy; psychotic disorders; using anti-psychotic drugs; hepatic failure; elevated liver enzymes;renal failure; cardiac dysrhythmia; hospital admission more than 5 days; infection in last 14 days; drug allergic reaction to lidocaine; blood transfusion in last week; blood transfusion during or after surgery; surgery duration more than 4 hours; drug abuse are exclusion criteria

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization using randomized number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Shahid Beheshti University of Medical Sciences

Street address

Vice chancellor for research, Shahid Beheshti University of Medical Sciences, Velenjak Street

City

Tehran

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

IR.SBMU.SM.REC.1394.98

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

Primary outcomes

1

Description

neutrophil to lymphocyte ratio

Timepoint

0, 6, 24, 48 hours and 14 days after surgery

Method of measurement

Calculation of the ratio by researcher

2

Description

Glasgow prognostic score

Timepoint

0, 6, 24, 48 hours and 14 days after surgery

Method of measurement

Calculation of the score by researcher

Secondary outcomes

1

Description

C reactive protein

Timepoint

0, 6, 24, 48 hours and 14 days after surgery

Method of measurement

Based on mg/dL using laboratory kit

2

Description

Albumin

Timepoint

0, 6, 24, 48 hours and 14 days after surgery

Method of measurement

Based on mg/dL using laboratory kit

3

Description

Complete blood count (CBC)

Timepoint

0, 6, 24, 48 hours and 14 days after surgery

Method of measurement

Based on count/mm3 using laboratory kit

Intervention groups

1

Description
After inducing anesthesia using midazolam 0.02 mg/kg, fentanyl 2-4 µg/kg, propofol 1-2 mg/kg and atracurium 0.5 mg/kg, in intervention group, 1.5 mg/kg/hr IV lidocaine was infused intravenously.
Category
Treatment - Drugs

2

Description
After inducing anesthesia using midazolam 0.02 mg/kg, fentanyl 2-4 µg/kg, propofol 1-2 mg/kg and atracurium 0.5 mg/kg, in control group, normal saline with the same volume and rate as 1.5 mg/kg/hr IV lidocaine was infused intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hosein Hospital
Full name of responsible person
Dr. Elham Memary
Street address
Shahid Madani Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziyayi
Street address
Vice chancellor for research, 3rd floor, Medical School, Shahid Beheshti University of Medical Sciences, Velenjak, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty