Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effect of perioperative intravenous lidocaine in modified radical mastectomy on postoperative pain and immune function

Protocol summary

Study aim

Determine effect of intravenous lidocaine on postoperative pain severity and immune response in mastectomy surgery.

Design

This is a double blinded randomized clinical trial that will be done on 50 patients who will candidate for elective mastectomy.Patients will be randomly allocated into two groups those who received intravenous lidocaine (n=25) and control group (n=25).Anesthesiologist, patients, all of the collaborating personnel will be blinded to study's group of patients.20 min before general anesthesia, patients received 2mg/Kg bolus dose of lidocaine then intravenous infusion(1.5 mg/Kg) of lidocaine with infusion pump will be started till end of operation. Postoperative Pain severity according to VAS will be recorded and will be compared.Also, serum level of interleukin and 6 in the morning of operation and 24 hr post operation between both groups will be measured and compared.

Settings and conduct

This is a randomized, double blinded clinical trial , single center.For blindness, all of the drugs solution(lidocaine and normal saline) of this study will be prepared in 50 ml syringes that are equal in shape by only person who aware of study's groups .Anesthesiologist, patients all collaborate study's persons will not aware of patients group.

Participants/Inclusion and exclusion criteria

Inclusion criteria:All patients who will be candidate for elective mastectomy due to breast tumor Exclusion criteria:Emergency patient;History of cardiac arrhythmia;Diabetes mellitus; Immune suppressive drugs; Corticosteriods;NSAIDs,; Renal and Liver failure; Hypersensetivity to lidocaine or contraindication of use of lidocaine.

Intervention groups

Intervention group: 20 min before general anesthesia, patients received 2mg/Kg bolus dose of lidocaine then intravenous infusion(1.5 mg/Kg) of lidocaine with infusion pump will be started till end of operation.

Main outcome variables

Postoperative Pain severity according to VAS will be recorded and will be compared.Also, serum level of interleukin and 6 in the morning of operation and 24 hr post operation between both groups will be measured and compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121204011662N11**
Registration date: **2018-01-09, 1396/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-09, 1396/10/19**
Update count: **0**

Registration date

2018-01-09, 1396/10/19

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1231 8072

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sahmeddini@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date
2018-05-22, 1397/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of perioperative intravenous lidocaine in modified radical mastectomy on postoperative pain and immune function

Public title
Survey of the effect of the intravenous lidocaine during mastectomy on post operative pain and immune response.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who will be candidate for elective mastectomy due to breast tumor
Exclusion criteria:
Emergency patient;History of cardiac arrhythmia;Diabetes mellitus; Immune suppressive drugs; Corticosteriods;NSAIDs,; Renal and Liver failure; Hypersensetivity to lidocaine or contraindication of use of lidocaine.
Age
From **25 years** old to **75 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
For blindness, All of the drugs solution(lidocaine and normal saline) of this study will be prepared in 50 ml syringes that are equal in shape by only person who aware of study's groups .Anesthesiologist, patients all collaborate study's persons will not aware of patients group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz Medical School Research Ethic Committee
Street address
3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
197871345
Approval date
2017-10-16, 1396/07/24
Ethics committee reference number
IR.SUMS.MED.REC.1396.87

Health conditions studied

1

Description of health condition studied
Postoperative pain and Immune response
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Severity of postoperative pain
Timepoint
Every 15 min in the recovery room, then 4, 8, 12,24 hr post operation in ward.
Method of measurement
Visual analog Scale

2

Description
immune system response
Timepoint
In the morning of operation and 24 hr post operation.
Method of measurement
Interleukin 1 and 6 Kit

Secondary outcomes

1

Description

Patients satisfaction from pain control managment

Timepoint

24 following operation

Method of measurement

Totally unsatisfactory=0, unsatisfactory=1,None=2,Satisfy=3, Completely satisfy=4

Intervention groups

1

Description

Intervention group: 20 min before general anesthesia, patients received 2mg/Kg bolus dose of lidocaine then intravenous infusion(1.5 mg/Kg) of lidocaine with infusion pump will be started till end of operation.

Category

Treatment - Drugs

2

Description

Control group: In this group 20 minutes before general anesthesia, patients received 2ml /Kg bolus dose of the physiologic saline then intravenous infusion(1.5 ml/Kg/hr) of the physiologic saline with infusion pump will be started till end of operation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Training and Medical Center

Full name of responsible person

Mohammad Ali Sahmeddini

Street address

Zand Blv

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz University Of Medical Sciences building, Zand Blvd.

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Web page address

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Grant name

Grant code / Reference number

Grant No:14165

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahmeddini

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
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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