Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Block of Serratus Anterior Plane As Postoperative Analgesia of Modified Radical Mastectomy

Protocol summary

Study aim
This study analyzes serratus anterior plane block as postoperative analgesia in Modified Radical Mastectomy Surgery by assessing the level of pain, side effects, and complications.

Design
Randomized double blind clinical trial with parallel group design of 44 patients

Settings and conduct
This study was conducted ad Kariadi General Hospital, SAP block performed in the operating room under General Anesthesia, Numeric Rating Pain Score were assessed at the inpatient ward 4, 8, 12 and 24 hours after surgery

Participants/Inclusion and exclusion criteria
Inclusion criteria in this study are patients who underwent MRM, aging 18-59 years with American Society of Anesthesiologist (ASA) class I or II. The patient can also speak verbally and use Numerical Rating Scales (NRS). Patients with opioid allergies and taking drugs that were not match the research protocol were excluded from this study.

Intervention groups
The treatment group of SAP block were induced with anesthesia drugs propofol 2 mg/kg BW, rocuronium 0.6 mg/kg BW and were given maintenance with sevoflurane 1 MAC, intravenous paracetamol 1000 mg, and ketorolac intravenously 30 mg. Then were given SAP block using isobaric bupivacaine 0.25% with 20 cc volume

Main outcome variables
Numeric Rating Scale Pain Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230219057451N2**
Registration date: **2023-08-09, 1402/05/18**
Registration timing: **retrospective**

Last update: **2023-08-09, 1402/05/18**
Update count: **0**

Registration date
2023-08-09, 1402/05/18

Registrant information

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Taufan Pramadika

Name of organization / entity
Diponegoro University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-02, 1400/05/11

Expected recruitment end date
2022-01-02, 1400/10/12

Actual recruitment start date
2021-08-14, 1400/05/23

Actual recruitment end date
2021-10-30, 1400/08/08

Trial completion date
2021-11-20, 1400/08/29

Scientific title
Block of Serratus Anterior Plane As Postoperative Analgesia of Modified Radical Mastectomy

Public title
Peripheral Nerve Block of Serratus Anterior Plane As Analgesia After Modified Radical Mastectomy Surgery

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients who underwent MRM Age 18-59 years old Patient with American Society of Anesthesiologist (ASA) class I or II The patient can also speak verbally and use Numerical Rating Scales (NRS).
Exclusion criteria:
Patients with opioid allergies were excluded from this study Patient is known to be taking drugs that are not the research protocol
Age
From **18 years** old to **59 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization that we used was simple random sampling procedure. The randomization process was performed using numbers randomized by an internet-based computer program (www.randomization.com). The numbers were placed in a sealed envelope. The sealed envelope was opened when the patient arrived at the pre-operation room; then, the patient asked to take one of the papers containing a number. The intervention was given to the subjects selected through randomization based on number in the sealed envelope. Odd numbers were the intervention group, even numbers were the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This was double blind clinical trial. The patients who reported their Numeric Rating Scales (NRS) Pain Score scores were blinded to the group assignment because the patient did not know whether they were the control group or the intervention group. The Serratus Anterior Plane Block was performed when patient still unconscious under General Anesthesia. The Investigator and Outcome assessors also blinded to group assignment because NRS pain score assessed after the surgery inthe inpatient ward. So, the outcome assessor and investigator didn’t know which one is the intervention group or control group
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Health Research Ethic Committee RSUP DR. KARIADI SEMARANG
Street address
No 16, DR Sutomo Street
City
Semarang
Postal code
50244
Approval date
2021-06-23, 1400/04/02
Ethics committee reference number
No.843/EC/KEPK-RSDK/2021

Health conditions studied

1

Description of health condition studied
Breast Cancer Patient underwent Radical Mastectomy Surgery
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Numeric Rating Scale Pain Score
Timepoint
4 hours, 8 hours, 12 hours, 24 hours after surgery
Method of measurement
Numeric Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group : The treatment group were induced with anesthesia drugs propofol 2 mg/kg BW, rocuronium 0.6 mg/kg BW and were given maintenance with sevoflurane 1 MAC, intravenous paracetamol 1000 mg,

and ketorolac intravenously 30 mg. Then were given SAP block using isobaric bupivacaine 0.25% with 20 cc volume

Category
Treatment - Drugs

2

Description
Control group: The control group were induced with anesthesia drugs propofol 2 mg/kg BW, rocuronium 0.6 mg/kg BW and were given maintenance with sevoflurane 1 MAC, intravenous paracetamol 1000 mg, and ketorolac intravenously 30 mg. Then were given morphine 20mcg/kg/h continuous infusion as analgesic

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
RSUP dr Kariadi General Hospital

Full name of responsible person
Chandra Hermawan Manapa

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
DIponegoro 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
Diponegoro University

Full name of responsible person
Taufan Pramadika

Position
Student

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Block of serratus anterior plane as postoperative analgesia of modified radical mastectomy
When the data will become available and for how long
3 months after publication
To whom data/document is available
for people working in academic institutions or people working in businesses can also apply to receive it
Under which criteria data/document could be used
as long as they asked permission to the author of this research
From where data/document is obtainable
they could obtain by contacting us via email
What processes are involved for a request to access data/document
first they must ask permission via email then they made us formal letter to use this data
Comments