

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

Registration timing: **retrospective**

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 at 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

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

Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230219057451N2**

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

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 in the 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

Diponegoro University of Medical Sciences

Full name of responsible person

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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

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Latest degree

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Person responsible for updating data

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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