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Regional anesthesia in breast reconstructive surgery

Submission date
28/11/2024

Recruitment status
No longer recruiting

Registration date
28/01/2025

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to find out if using regional anesthesia during breast reconstruction surgery can lower pain levels, reduce the need for painkillers and opioids, decrease complications after surgery, and shorten hospital stays.

Who can participate?
Women aged 18 to 90 years who are scheduled for radical breast surgery (such as Skin-Sparing Mastectomy or Nipple-Sparing Mastectomy) or standard mastectomy (Modified Radical Mastectomy) with primary reconstruction using a prosthesis or expander placed beneath the pectoral muscle.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive the standard general anesthesia, while the other group will receive regional anesthesia. Both groups will complete a pain questionnaire before surgery and at 6 and 24 hours after surgery. The study will also record the use of painkillers and opioids, any complications within 24 hours after surgery, and the length of hospital stay.

What are the possible benefits and risks of participating?
Participants who receive regional anesthesia may experience lower pain levels after surgery. There are no additional risks compared to the usual procedure.

Where is the study run from?
University Hospital Dubrava/Klinička Bolnica Dubrava (Croatia)

When is the study starting and how long is it expected to run for?
October 2021 to June 2024

Who is funding the study?
University Hospital Dubrava/Klinička Bolnica Dubrava (Croatia)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Regional anesthesia in breast reconstructive surgery

Study objectives
Regional anesthesia in breast reconstructive surgery is associated with lower pain score, lower opioid usage, lower complication rate and shorter hospital stay.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/02/2022, Ethics committee of Clinical Hospital Dubrava (Avenija Gojka Suska 6, Zagreb, 10000, Croatia; +385 1 290 2726; povjerenstvo.eticko@kbd.hr), ref: 2022/2701 04

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Patients will be randomly assigned to one of two groups via blinded selection.
1. First group: Patients will undergo the standard anesthetic protocol used for general anesthesia.

2. Second group: Patients will receive regional anesthesia following this protocol:
o Thoracic paravertebral block with 0.3 mL/kg of ideal body weight of 0.5% levobupivacaine + 4 mg dexamethasone + epinephrine (1:200,000), followed by:
o Additional pectoral block comprising:
0.2 mL/kg of ideal body weight of 0.5% levobupivacaine + 4 mg dexamethasone + epinephrine (1: 200,000) administered between the pectoralis major and pectoralis minor muscles.
A supplementary block between the pectoralis minor and serratus anterior muscles with 0.2 mL /kg of ideal body weight of 0.5% levobupivacaine + 2 mg dexamethasone + epinephrine (1: 200,000).

For premedication, Dormicum (Midazolam) 3–5 mg intramuscularly will be administered 30 minutes before the block (administered in the ward). During block administration, 1–3 mg Dormicum will be given intravenously. During surgery, deep sedation will be achieved with Propofol at a dose of 30–70 mcg/kg per minute, along with oxygen via mask at 12 L/min.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
levobupivacaine, dexamethasone, epinephrine, Dormicum (midazolam), propofol

Primary outcome(s)
Pain is measured using a visual analogue scale at baseline, 6 and 24h

Key secondary outcome(s))
Measured using patient records after hospital stay:
1. Opioid consumption
2. Duration of hospital stay

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Women aged 18–90 years scheduled for radical breast surgery (Skin-Sparing Mastectomy (SSM) or Nipple-Sparing Mastectomy (NSM)) or standard mastectomy (Modified Radical Mastectomy (MRM)) with primary reconstruction using a prosthesis or expander placed beneath the pectoral muscle

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
Female

Total final enrolment
50

Key exclusion criteria
Patients experiencing chronic pain or those undergoing pain therapy will not be included in the study.

Date of first enrolment
01/02/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Croatia

Study participating centre
Clinical Hospital Dubrava
Avenija Gojka Suska 6
Zagreb
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Sponsor information

Organisation
University Hospital Dubrava

ROR
https://ror.org/00mgfdc89

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Klinička Bolnica Dubrava

Alternative Name(s)
Clinical Hospital Dubrava, KBD

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Croatia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a non-publicly available repository. All data about each individual patient is stored in paper and as well in electronic form in our Regional Anesthesia folder on our Department disk.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			29/11/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes