

Regional anesthesia in breast reconstructive surgery

Submission date 28/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/01/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/02/2026	Condition category Cancer	<input type="checkbox"/> Individual participant data

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?
Domagoj Eljuga, deljuga@gmail.com

Contact information

Type(s)

Principal investigator

Contact name

Dr Domagoj Eljuga

ORCID ID

<https://orcid.org/0000-0001-8902-0072>

Contact details

Maksimirska cesta 88
Zagreb
Croatia
10000
+385 91 383 99 50
deljuga@gmail.com

Type(s)

Public

Contact name

Dr Krešimir Martić

ORCID ID

<https://orcid.org/0009-0002-6025-4806>

Contact details

Nova cesta 136A
Zagreb
Croatia
10000
+38598 752178
kmartić76@gmail.com

Type(s)

Scientific

Contact name

Dr Ivo Jurisic

ORCID ID

<https://orcid.org/0000-0002-1755-0039>

Contact details

Ogulinska 4a
Zagreb
Croatia
10000
+385 98 9050015
ivojurisic1@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)

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

Mixed

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

Croatia

10000

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?
Results article		01/06/2025	02/02/2026	Yes	No
Participant information sheet			29/11/2024	No	Yes