ISRCTN14701722 https://doi.org/10.1186/ISRCTN14701722

# Regional anesthesia in breast reconstructive surgery

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 28/11/2024 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/01/2025 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/02/2026 | Cancer | |

**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

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# Additional identifiers

# 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

### Primary study design
Interventional

### Study design
Interventional randomized controlled trial

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