

**Official Title of the study:**

Prospective, Randomized Comparative Study of an Anesthesiological, Ultrasound-Guided „Erector Spinae Plane Block“ (ESPB) Versus a Surgical, Thoracoscopically-Guided „Intercostal Nerve Block“ (ICNB) in „Video-Assisted Thoracoscopic“ (VATS) Procedures, Evaluating Postoperative Analgesic Consumption, Postoperative Pain Perception, and Duration of the Procedure

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09 Apr 2026

# **Patient Information and Informed Consent for the Research Project: Prospective, Randomized Comparative Study of an Anesthesiological, Ultrasound-Guided „Erector Spinae Plane Block“ (ESPB) Versus a Surgical, Thoracoscopically-Guided „Intercostal Nerve Block“ (ICNB) in „Video-Assisted Thoracoscopic“ (VATS) Procedures, Evaluating Postoperative Analgesic Consumption, Postoperative Pain Perception, and Duration of the Procedure**

## **Patient Information**

Dear Patient,

We would like to ask you whether you would be willing to participate in a scientific study. This document contains all important information about the study. Please read this information carefully. Your physician will discuss the study with you and answer your questions.

Approximately 72 participants will take part in this study.

This study is planned by the Department of Anesthesiology, Intensive Care Medicine and Pain Therapy at Sana Klinikum Offenbach and is scheduled to be conducted over a period of one year. The study is funded internally by our institution. The study has been submitted to the responsible ethics committee. No objections have been raised.

Your participation in this study is voluntary. If you choose not to participate or if you withdraw your consent later, you are not required to provide a reason. You will not experience any disadvantages. In particular, your decision will not affect your medical treatment or your relationship with your treating physician.

If you have any questions about the study now or at a later time, you are welcome to contact us:

Sana Klinikum Offenbach

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## **Why is this study being conducted?**

Dear Patient,

You are scheduled to undergo a video-assisted thoracoscopic (VATS) procedure. This operation is performed under general anesthesia.

In addition to commonly used pain medications administered during general anesthesia and after surgery, a variety of regional anesthesia techniques are available for pain management. These techniques can significantly reduce or even completely eliminate postoperative pain.

For your procedure, so-called chest wall blocks are suitable.

Chest wall blocks have been used in medicine for decades and have been further improved in recent years through the use of ultrasound. Their effectiveness has been investigated and

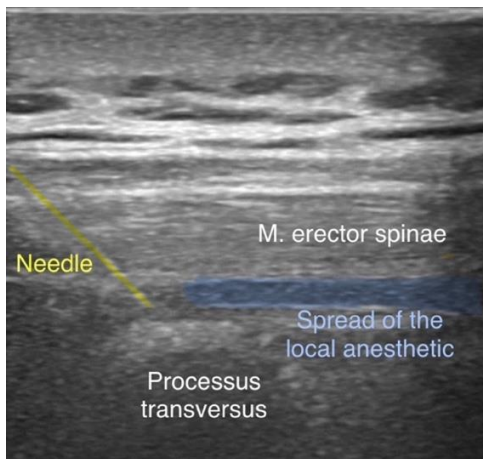
confirmed in numerous scientific studies. Studies have also shown that they can facilitate breathing and accelerate the improvement of lung function. Therefore, chest wall blocks are now considered an established and reliable method and are routinely used as an adjunct to general anesthesia.

In these procedures, local anesthetic is administered specifically near nerves that supply the chest wall. This blocks pain signals in these areas. The need for strong pain medications such as opioid derivatives, which can be associated with significant systemic side effects, is significantly reduced.

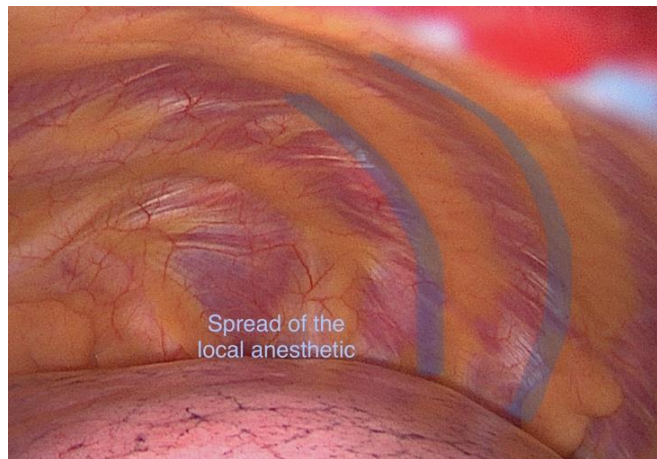
Among chest wall blocks are the „Erector Spinae Plane Block“ (ESPB) and the „Intercostal Nerve Block“ (ICNB). Both techniques have been shown in the literature to be safe and effective.

The ESPB is performed by anesthesiologists under ultrasound guidance before the induction of general anesthesia. Using ultrasound, the long back muscle called the erector spinae is identified, and local anesthetic is injected into the tissue layer beneath it. The anesthetic spreads along this layer and can reach multiple nerve branches supplying the chest wall at different levels. The needle used for the procedure is visualized along its entire length at all times using ultrasound, and the injection of the local anesthetic is performed under direct ultrasound visualization. This helps to minimize risks and complications.

The ICNB is performed by surgeons under thoracoscopic guidance after induction of general anesthesia and immediately before the start of surgery. For the minimally invasive „keyhole“ procedure, a camera (thoracoscope) is inserted into the chest through a small incision. Before the actual surgery begins, the inner side of the ribs is visualized, and local anesthetic is injected under direct visual control at five levels along the intercostal nerves. This also minimizes risks and complications.



Ultrasound image of ESPB



Thoracoscopic image of ICNB

At Sana Klinikum Offenbach, both techniques are routinely used. Accordingly, there is extensive experience with both methods, which further enhances patient safety. According to current knowledge, there are no clearly established advantages or disadvantages of one technique over the other.

The aim of this study is to determine which of the two techniques is more effective in terms of pain relief and reduction of analgesic consumption. To our knowledge, this has not yet been sufficiently investigated.

## How is the study conducted?

Adult patients undergoing VATS surgery for lung resection and who provide consent will be included in the study.

The following exclusion criteria apply:

- Lack of informed consent
- Language barrier
- Pregnancy or breastfeeding
- Known allergy to local anesthetics used in the study
- Infection at the injection site(s)
- History of complex chest wall surgery
- Revision surgery with a prior operation within the last 6 months
- Intraoperative conversion to open thoracotomy
- Chronic pain syndrome
- Fibromyalgia
- Chronic opioid use
- Chronic alcohol abuse
- Chronic substance abuse (e.g., THC, amphetamines, cocaine)
- History of psychiatric disorders (e.g., depression, schizophrenia)
- Impaired consciousness, cognition, or ability to communicate
- Known coagulopathy (including platelet count  $< 80,000/\mu\text{L}$  or prolonged PTT/aPTT  $> 1.5\times$  the upper limit of normal)
- Ongoing therapeutic anticoagulation

Participation in the study will last approximately 24 hours for each participant.

After you have agreed to participate, you will be randomly assigned to one of two groups.

In one group, the chest wall block will be performed as an ESPB before induction of general anesthesia by anesthesiology staff. In the other group, the surgical team will perform an ICNB before the start of the operation while you are already under general anesthesia.

At predefined time points (1 hour, 2 hours, 12 hours, and 24 hours after surgery), you will be visited by the in-house anesthesiology pain service. Pain intensity will be assessed using a standardized pain questionnaire, and analgesic consumption will be recorded. Each assessment will take approximately 5 minutes.

Participation is voluntary. You may withdraw your consent at any time without giving reasons.

Allocation to the two groups is random, comparable to flipping a coin. The remaining treatment is identical in both groups. Randomization ensures comparability between the groups. The probability of being assigned to either group is equal.

## Is there any personal benefit from participation?

Both regional anesthesia techniques are already routinely explained to and performed on patients independently of this study. Reduction of pain perception and analgesic consumption contributes to improved patient satisfaction and is an integral part of modern multimodal pain

therapy. You will not derive any direct personal health benefit from participating in this study. However, the results may help improve treatment for future patients.

#### What risks are associated with participation?

Since both procedures are already established in our clinic, participation in the study does not involve any additional risks beyond standard medical care.

In addition to the risks associated with the surgical procedure and general anesthesia, the following potential risks may occur in the context of chest wall blocks:

Allergic reaction/anaphylaxis to the local anesthetic, local anesthetic toxicity due to accidental injection into a blood vessel or increased systemic absorption, bleeding/hematoma, infection, pneumothorax (lung collapse), injury to nerves or vessels in the puncture area, failure of analgesic effect

#### Do additional costs arise?

Participation in the study will not result in any additional costs for you or your health insurance.

#### Information on Data Protection

In this study, Sana Klinikum Offenbach is responsible for data processing. The legal basis for processing is your consent (Art. 6(1)(a), Art. 9(2)(a) GDPR). All data will be treated confidentially at all times.

Data will be collected exclusively for the purposes of this study and used only within this context.

The data collected include personal information such as name, address, date of birth, and sensitive health data.

All data that could directly identify you (e.g., your name or date of birth) will be replaced by an identification code (pseudonymized). Identification is only possible via a pseudonymization list, which is accessible only to authorized study personnel.

The data collected in this study will be stored at the study center of Sana Klinikum Offenbach.

Personal data will be stored only as long as necessary for the stated purpose and will be deleted no later than 10 years after completion or termination of the study.

No personal data will be transferred to other institutions within Germany, the EU, or outside the EU, nor to international organizations.

Research data may be used for scientific publications and/or made available to other researchers in anonymized form, without any possibility of identifying individual participants.

Your consent to data processing is voluntary. You may withdraw it at any time without providing reasons and without any disadvantages. After withdrawal, no further data will be collected. The legality of data processing carried out before withdrawal remains unaffected.

You may request deletion of your data. Data may continue to be used in anonymized form if you agree at the time of withdrawal.

You have the right to obtain information about your data, including a free copy, and to request correction, data lock, restriction of processing, deletion, or data transfer.

For questions or withdrawal, please contact:

Sana Klinikum Offenbach

Department of Anesthesiology, Intensive Care Medicine and Pain Therapy

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The study does not plan or intend to contact you again after completion.

Please note that your rights may be restricted in individual cases if there is a public interest in research or if third-party rights must be considered.

Please contact the data protection officer (DPO) for data protection inquiries:

Lukas Mempel, Oskar-Messer-Strasse 24, 85737 Ismaning, corporate data protection officer (DPO), SANA Kliniken AG

You also have the right to lodge a complaint with a supervisory authority. A list of data protection supervisory authorities in Germany can be found at:

[https://www.bfdi.bund.de/DE/Infothek/Anschriften\\_Links/anschriften\\_links-node.html](https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html)

You can contact the supervisory authority responsible for you at:

The Hessian Commissioner for Data Protection and Freedom of Information

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65021 Wiesbaden

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**Informed Consent**

I have been informed about the study by \_\_\_\_\_.

I have received and read the written patient information and consent form for the above-mentioned study. I have been fully informed in writing and orally about the purpose and procedures of the study, the risks and benefits of participation, and my rights and obligations. I had the opportunity to ask questions, and these were answered satisfactorily.

In addition to the written information provided, the following points were discussed:

\_\_\_\_\_  
\_\_\_\_\_

My participation is voluntary. I may withdraw my consent at any time without giving reasons and without any disadvantages.

The processing and use of personal data for the above-mentioned study will be carried out exclusively as described in the study information.

**I hereby consent to the processing of my personal data as described above, in particular including health data.**

**I hereby consent to participate in the above-mentioned study.**

\_\_\_\_\_  
Name of the **Participant** (block letters)

\_\_\_\_\_  
Place, Date

\_\_\_\_\_  
Signature of the **participant**

\_\_\_\_\_  
Name of the **person obtaining informed consent** (block letters)

\_\_\_\_\_  
Place, Date

\_\_\_\_\_  
Signature of the **person obtaining informed consent**