INFORMED VOLUNTARY CONSENT FORM

Official Title of the Study:
Comparison of the Effect of Preoperative and Postoperative Erector Spina Plan Block and Paravertebral Block on Postoperative Pain in Video Assisted Thoracic Surgery (VATS)

NCT Numarası: NCT06488014

Date: 05.06.2024

Dear Volunteer,

You are invited to participate in the above-mentioned research study planned at Ankara University Faculty of Medicine, Department of Anesthesiology and Reanimation. The estimated number of participants expected to be enrolled in this study is 80.

Before deciding whether to participate in this study, it is important that you understand why the research is being conducted and that you make your decision freely based on the information provided.

Please read the following information carefully. If you have any questions, please ask and request clear explanations.

Thoracic surgical procedures are associated with significant pain in both the early and late postoperative periods. Although intravenous systemic analgesics are widely used, they are often insufficient and have led us to seek more effective methods. These include central nerve blocks such as epidural analgesia and peripheral nerve blocks such as the paravertebral block and erector spinae plane block.

Nerve blocks work by interrupting the transmission of pain signals carried by nerves to the central nervous system. The aim is to prevent pain stimuli from reaching the brain.

In our routine clinical practice, after the patient is anesthetized, we combine two nerve block applications: one before the surgical incision and one at the end of surgery. At the level corresponding to your surgical incision, local anesthetic medications are administered near the transverse processes of the vertebrae and between muscle planes, where the spinal nerves exit the spinal cord.

The purpose of this study is to monitor, record, and compare the effects of the two methods routinely used in our clinic: the paravertebral block and the erector spinae plane block. Allocation of patients to the study groups will be performed randomly.

If you agree to participate in the study, you and/or your first-degree relative will be asked to sign this consent form during the preoperative preparation phase before surgery.

Your demographic data, surgical information, intraoperative vital signs, and monitoring results will be recorded. No additional invasive procedures will be performed beyond the routine treatment methods.

After surgery, you will be visited in your room at specified intervals for 72 hours to assess your pain. In addition, you will be contacted by telephone at the 3rd and 6th postoperative months for chronic pain assessment.

Participants will be followed only within the scope of routine treatment processes and will not be required to spend additional time. No additional risk beyond the routine treatment process is expected for volunteers participating in the study.

If you choose not to participate in the study or decide to withdraw from it, you will not face any negative consequences. Apart from data recording, all routine treatment procedures will continue as usual.

You will not receive any payment for participating in this study, and no fees will be charged to you or your social security institution.

Participation in this research is entirely voluntary. You may refuse to participate or withdraw from the study at any time after it has begun. The results of this study will be used for scientific purposes. If you withdraw from the study or are withdrawn by the investigator, your data will not be used. However, once the data have been anonymized, withdrawal of your data will no longer be possible. All information obtained from you will be kept confidential, and if the research is published, your identity will remain confidential.

If new information related to the study becomes available that may affect your willingness to continue participation, you or your legal representative will be informed in a timely manner.

If you require further information about the study, your rights, or any adverse events related to the study, you may contact the following individuals, who are available 24 hours a day:

Research Assistant Dr. .....
Research Assistant Dr. .....

“I have read (or have been read aloud) the above information that must be provided to volunteers before participation in the study. I have asked the investigators about any issues I considered unclear and have received satisfactory answers. I believe that I fully understand all written and verbal explanations provided to me.

I have been given sufficient time to decide whether or not to participate in the study. I understand that I may withdraw from the study at any time, with or without giving a reason.

Under these conditions, I voluntarily agree, without any pressure or coercion, to the use, presentation, and publication of my personal data obtained within the scope of this research for scientific purposes, provided that confidentiality rules are respected.”

Signature/Date	Signature/Date
Name/Surname of Volunteer	Name/Surname of Investigator

Note: This form must be prepared in two copies; one signed copy should be given to the participant.