

Here is the English translation of the medical consent form you provided:

The form is written in the masculine form for convenience only but is intended for both genders.

You are invited to voluntarily participate in a medical trial. A medical trial is an innovative procedure that is not recognized, not accepted, or not yet approved for routine treatment in Israel, and therefore there is uncertainty regarding its safety or efficacy. This form explains the trial you have been invited to join. We ask you to read the information carefully and discuss it with anyone you choose: friends, relatives, and doctors or healthcare professionals who are not directly involved in the trial. Additional information about the trial and answers to questions can be obtained from the trial physician or their representatives.

Before making a decision to join the trial, it is very important to know the existing risks and benefits in order to make an informed decision. This process is called "Informed Consent."

Your participation in the trial is of your own free will, and you have the right to choose not to participate in it and not to sign the consent form. You can withdraw from the trial at any time, without giving a reason. Your decision to refuse or withdraw will not have a negative impact on the medical treatment you receive now or in the future, and the treatment options available to you will be explained to you.

If you are interested in participating in the trial, you will be asked to sign this form. You will receive a signed copy to keep, and the original will be kept at the medical institution.

First Name: _____

Last Name: _____

ID Number: _____

Address: _____



1.1.1 1) Information About the Trial

Study Number: 0349-24-SOR

1.1) Trial Subject: A prospective comparison between the efficacy of a continuous paravertebral (PVB) peripheral block and the efficacy of a continuous erector spinae plane (ESP) peripheral block, in patients undergoing robotic thoracoscopic surgery.

1.2) The investigator, Dr. Alexander Smirnov, received approval to conduct the trial from the Institutional Helsinki Committee and from the Director of the Soroka Medical Center in accordance with the Public Health Regulations (Medical Trials in Human Subjects) 1980.

1.3) Purpose of the Trial: Comparison between the efficacy of a continuous paravertebral (PVB) peripheral block and a continuous erector spinae plane (ESP) peripheral block with a catheter in robotic thoracic surgeries.

1.4) The Treatment in the Trial: Thoracic surgeries are surgeries with a highly significant postoperative pain component. Therefore, as part of an approach to pain management designed to reduce the consumption of narcotic preparations (drugs) and reduce the incidence of side effects from these preparations, performing peripheral blocks for postoperative pain relief is recommended. The recommended peripheral blocks in these surgeries are the paravertebral block (PVB) and the erector spinae plane block (ESP) with continued continuous infusion via a catheter that remains in these spaces after the block is performed for 5-7 days to achieve continuous pain relief.

1.5) Number of Participants in the Trial: All patients will be divided into 2 groups; there will be 30 patients in each group, totaling 60 patients.

1.6) Expected Duration of the Trial: From the day of surgery until discharge home.

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1.7) Trial Methods: After the patients sign, general anesthesia will be administered with the patient turned on their side, as is customary in these surgeries. A continuous block will be performed with the insertion of a catheter for continuous infusion. It should be noted that both blocks performed are effective in thoracic surgeries and have been proven by many studies to be effective in reducing pain. Currently, there is no preference in the literature for a specific block, and usually, the type of block performed is at the discretion of the anesthesiologist. The choice of the type of block that will be performed for the patient in each surgery will be selected by randomization before the surgery, and the patient will receive information about the type of block to be performed in advance. During the surgery, the anesthesiologist will monitor the amount of pain medication consumption and hemodynamic parameters. In addition, parameters will be monitored by the NOL system to evaluate intraoperative pain. After the surgery, the patients will be transferred to recovery. The recovery team will monitor pain levels. Furthermore, after transfer to the department, the patients will receive repeated doses of local anesthesia via the catheter for pain relief, as is customary at Soroka Hospital. The catheter will remain in place until the decision to discharge the patient from the cardiothoracic department or up to 7 days after its insertion, whichever comes first. As long as the catheter is in place, there is an option to add pain relief as needed on top of the regular treatment. At any stage, the patient will receive additional pain treatment if needed. They will also receive a clear explanation from the attending physician regarding continued treatment via the catheter.

1.8) What is your responsibility as a participant in the trial: Compliance with the study requirements, cooperation, and providing information regarding pain levels and satisfaction with the treatment.

1.9) What are the known risks and/or expected discomforts resulting from participation in the trial? Peripheral blocks are procedures performed routinely in the hospital, and it is known that the chances of side effects are relatively rare (around 0.2%). Known side effects are:

1. Infection in the area where the block is performed.
2. Damage to internal organs (lung) during the execution of the block.



3. Direct nerve injury with a needle.
4. Allergic reactions to the materials administered in the block.
5. Drop in blood pressure and dizziness. *In addition, there may be unknown/unforeseeable risks.*

1.10) What are the expected benefits to you as a participant or to others in your condition, resulting from the trial? It is known that peripheral blocks are significantly effective in reducing pain levels after surgery, reducing the amount of painkillers given and their side effects, decreasing the likelihood of nausea and vomiting, enabling faster mobilization, as well as decreasing postoperative respiratory complications.

1.11) Are there alternative treatments? There is no good alternative to a peripheral block. In the past, epidural anesthesia was performed, but the risks for this procedure are higher, and it has been proven by many studies that pain relief from epidural anesthesia is not more effective than a peripheral block. It will be explicitly explained to the patient that as a patient in the study, there is no advantage simply by participating in the study because a peripheral block for pain relief will be performed anyway by the anesthesiologist as standard practice even if the patient does not agree to participate in the study. The patient has the option to withdraw from the study at any stage; however, the treatment via the catheter will not change in any way, and the patient will receive standard treatment, but the data will not be collected or entered into the study. The investigator will explain the risks and benefits of the available treatment options to you.

1.12) Under what circumstances might your participation in the medical trial be terminated by the decision of the investigator or the sponsor? In the event of an inability to obtain reliable information due to the patient's condition. Participation in the study is free of charge.

1.1.2 2) Samples and Genetics

2.1) The study does not include information on samples and/or genetic testing.

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1.1.3 3) General Information

3.1) For any problem related to the medical trial, you may contact the investigator 24 hours a day by phone at: **050-390-1110**. In any case of a medical problem, injury, or other health event during the trial period, you must report it immediately in order to receive appropriate medical treatment, as well as further details on rights in this context.

3.2) The investigator will transfer information about your participation in the study (including the very performance of the genetic test) to your treating physician in the community for the purpose of awareness and medical follow-up. If clinically significant medical findings are discovered during the trial that were not previously known, the information (excluding genetic findings) will be provided to the community physician. Positive results for diseases requiring reporting by law will be sent to the Ministry of Health (e.g., Hepatitis, Tuberculosis, Measles, HIV, etc.).

3.3) New information that could affect the decision to participate or continue in the trial will be brought to your attention as soon as possible.

3.4) Within the framework of the study, you may be asked to answer a questionnaire. You may choose not to answer all the questions in the questionnaire or part of them.

3.5) The trial sponsor, Dr. Alexander Smirnov, pays the medical institution for the costs involved in conducting the trial. The investigator has an affiliation with the trial sponsor; the principal investigator is the trial sponsor.

3.6) The trial sponsor will provide the study product free of charge for the entire duration of the trial.

3.7) The trial sponsor and the medical institution have arranged for insurance coverage in the event of damage caused by conducting the trial.

3.8) There is a possibility that you will continue to receive the study product free of charge even after the conclusion of the medical trial for a period of up to three years from the end of the trial. This option to receive the study product (within the framework of a follow-up

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protocol) includes several conditions and is subject to the discretion of the investigator and the medical institution:

- It is clearly known that you took the study drug at the prescribed dose.
- The investigator recommends continuing this treatment.
- The study product has not yet been approved for marketing in the State of Israel for the requested indication and has not yet been included in the healthcare basket.

3.9) There are situations where the sponsor will not provide the product after the end of the trial:

- Development of the product has been discontinued, or the medical trials on the product did not yield the anticipated results.
- Administering the study product for a prolonged period is not suitable for your treatment and may harm your health.

3.10) The results of the trial may be of value and can be used as part of a patent, or the development of drugs, medical preparations, etc. Participants in the trial have no rights regarding patents, drugs, or preparations that will be developed as a result of the trial they participated in.

3.11) A description of this medical trial appears on the Ministry of Health's clinical trials website: MyTrials. The website will not include information that could identify you. You can search this website at any time.

1.1.4 4) Maintaining Privacy and Confidentiality of Information

4.1) In the study you have been asked to participate in, medical and personal information is collected as part of the trial. This information is kept in a medical record, and it is the responsibility of your treating team to maintain medical confidentiality. You have the right to receive information from the medical record in accordance with the Patient's Rights Act. If you are aware that the information in the medical record is incorrect or incomplete, you must inform the treating team.

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4.2) Information such as: medical test results, administration of preparations, accessories or implants, execution of experimental treatments or procedures, and the like will be kept in the medical record.

4.3) Your consent to participate in the trial also constitutes consent that medical and personal information collected during the trial will be transferred to an external body, which will use it for data processing. The information will be transferred to the external body only when it is coded. The information will not include: your first name, your last name, ID number, residential address, or any other identifying number given to you by state authorities. Generally, coded information is considered identifiable information. The link between the code and your identifying details will be kept securely by the principal investigator in Israel. In certain cases, the decoding will be permitted by the investigator.

4.4) The coded data and information will be kept by the sponsor for a period of time defined by law (at least 15 years from the end of the study).

4.5) [Certain information collected during the study will not be provided to you, such as: pharmacokinetic test results, biological markers, etc.]

4.6) Viewing permissions, for the purpose of verifying the medical trial methods and data, will be granted only to authorized entities (for example: authorized representatives of the sponsor, the Helsinki Committee, the auditing body at the medical institution, and inspectors from health authorities). This access to your medical information will be conducted through the investigator, and in accordance with the laws and procedures for maintaining confidentiality.

4.7) Your identifying details will not appear in any scientific or other publication.

1.1.5 5) Withdrawal from the Medical Trial

At any stage of the trial, it is your right to withdraw from it by notifying the principal investigator or their representative. You are not obligated to explain why you withdrew. The investigator is permitted to use only samples and/or coded data collected up to the time of withdrawal. From the moment you have announced your withdrawal from the trial, no further information will be

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collected about you. However, if medically significant information regarding you is received, you will be contacted. It is your right to refuse to receive the information.

1.1.6 6) Fertility Information

[Information on fertility (including partners), future fertility / pregnancy / fetus or nursing infant:]
Not relevant

1.1.7 7) Documentation of Consent:

The Participant: By my signature, I declare that I have read the contents of this document, the trial has been explained to me, and I agree to participate in it.

Name (First and Last): _____ **Signature:** _____ **Date and Time:** _____

The Explaining Investigator: By my signature, I declare that I have verbally explained the trial to the participant in accordance with what is written in this form. I believe that the participant understood what was said, had enough time to read the form, and expressed their desire to participate in the trial.

Name (First and Last): _____ **Signature:** _____ **Date and Time:** _____ *(including stamp and license number)*

Independent Witness*: I, the undersigned, was present during the explanation of the medical trial, confirm that the content of this document was conveyed verbally in my presence to the patient, I received the impression that they understood it, and I heard the participant verbally express their consent to participate in the trial.

Name (First and Last): _____ **Signature:** _____ **Date and Time:** _____

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