INFORMED CONSENT FORM

The Effects of Combined Rectus Sheath and Ilioinguinal Nerve Blocks on Opioid Consumption in Patients Undergoing Hand-Assisted Laparoscopic Donor Nephrectomy: A Randomized Controlled Double-Blind Prospective Study

Initials of Volunteer:
Volunteer No.:

You are being invited to participate in a scientific research study. Before making your decision, it is important that you fully understand what this research involves and why it is being conducted. Please read the following explanations carefully; you may discuss it with your friends, family, and physician if you wish. If anything is unclear or if you would like more information, please ask us. Take time to consider whether or not you wish to participate in this study.

1. What is the purpose of this study?
Donor nephrectomy surgeries are traditionally performed through an incision from the lower anterior abdomen towards the groin. With advancing technology, surgical techniques, and patient expectations, there has been increased demand for less invasive procedures such as hand-assisted laparoscopic surgery, which involves small incisions in the abdominal wall. These incisions allow various kidney surgeries to be performed. Faster recovery and earlier discharge are targeted in the postoperative period. However, due to incisions involving the abdominal muscles, patients may experience pain postoperatively. Without adequate pain management, patients may suffer from severe pain, which can negatively affect recovery and increase the risk of complications. Regional anesthesia techniques have been used for postoperative pain control, but there is no ideal technique yet. The aim of this study is to determine whether applying local anesthesia between the abdominal muscles and to the groin area, in addition to general anesthesia, can reduce the need for narcotic pain relievers in the postoperative period for patients undergoing kidney surgery.

2. What procedures will be performed on me?
After being taken to the operating room preparation area, you will be asked to lie on your back. Once you are fully anesthetized under general anesthesia, ultrasound imaging will be used on your abdominal muscles. After identifying and confirming the three abdominal muscles on ultrasound, local anesthetic or saline will be injected between two of these muscles where the surgical pain originates. Then, an injection of either a painkiller or saline will be administered to the ilioinguinal nerve, which provides sensation to the groin area. The decision of whether you receive local anesthetic or saline will be made in advance by randomization using sealed envelopes. Neither you nor the healthcare personnel following you postoperatively will know the content of the injection, to prevent any potential bias during patient follow-up. Once data collection is complete, the type of injection received will be revealed and analyzed accordingly. After the injection, the surgical team will proceed with the operation. At the end of the surgery, you will be taken to the recovery room. There, you will be asked to rate your pain in the anterior abdominal wall and groin area on a scale of 0 to 10. If your pain score is 4 or higher, additional intravenous pain medication will be administered. The total amount of additional pain medication administered in the first 24 hours postoperatively and your reported pain scores will be recorded.

3. What do I need to do if I participate in this study?
You are not required to do anything. No fees will be charged to the volunteer.

4. How long will the study last, and how many volunteers will participate?
The study will last 6 months and will include 52 patients.

5. Are there any side effects from the procedures in this study? What happens if I experience these side effects?
If the local anesthetic used for pain enters the bloodstream, it may cause local anesthetic systemic toxicity. Routine postoperative monitoring is sufficient to detect any side effects. If this occurs, appropriate treatment (lipid solution) will be administered. The amount of local anesthetic used is below the toxic dose (3 mg/kg).
If the local anesthetic is accidentally injected into the nerve, short- or long-term nerve damage such as numbness or tingling may occur. Using ultrasound guidance for the injection minimizes this risk.
Infection at the injection site is another possible risk, which will be minimized by ensuring sterile conditions (sterile gloves, skin disinfection with iodine solution, sterile block needle, and sterile ultrasound probe cover).
These risks are common to all regional block techniques, and there are no additional or unique risks associated with the blocks being tested in this study.

6. Who will cover the cost of examinations, tests, and medications related to my participation? Will I need to pay anything?
Neither you nor your social security institution will incur any costs as a result of this study.

7. Will volunteers participating in the study be insured?
No.

8. Will my medical and personal information be kept confidential during this study? Who will have access to this information?
Your personal information will not be recorded for the study. Access to your medical information will be restricted to the responsible and assisting researchers only.

9. Will this study be approved by an official authority?
Yes, it will be approved by the Koç University Ethics Committee.

10. Who can I contact for more information or in case of an emergency?
You may consult your doctor for more information about the study or in case of any side effects during treatment.
For further information, you may contact Dr. Bahadır Hakan Oğuz directly or call +90 530 110 72 21.

(Participant/Patient Declaration)
I have been informed that a medical study will be conducted at Koç University Faculty of Medicine, Department of Anesthesiology and Reanimation. I have received the information about the study as outlined above. I have been invited to participate in this study as a "participant." I believe that all information I share with my physician during this study will be treated with the same level of confidentiality and respect as in regular medical care. I have been assured that my personal information will be carefully protected during the use of research results for educational and scientific purposes. I understand that I can withdraw from the study

at any time without providing any reason. (However, I understand it would be courteous to inform the researchers in advance to avoid disrupting the study.) I am also aware that the researcher may withdraw me from the study if deemed necessary, provided it does not harm my medical condition. I will not incur any financial responsibility for the study-related expenses, nor will I receive any payment. I have been assured that, should any health problems arise as a result of direct or indirect participation in this study, I will receive all necessary medical care, and I will not bear any financial burden related to this care. I understand that participation is voluntary and that I am under no obligation to participate. I have not been subjected to any pressure to participate. I also understand that refusing to participate will not affect my medical care or relationship with my physician. I have fully understood all the explanations provided to me. After taking time to consider, I have decided to participate as a “volunteer” in the research project mentioned above. I gladly and willingly accept this invitation. A signed copy of this form will be given to me.

Participant
Name, Surname:
Address:
Phone:
Signature:

Physician
Name, Surname:
Address:
Phone:
Signature: