Cover Page for ClinicalTrials.gov Posting

Official Title:
Comparison of the Transversus Fascial Plane Block and the Anterior Quadratus Lumborum Block for Lower Urogenital Surgery in Pediatric Patients

NCT Number:
NCT07256899

Document Type:
Informed Consent Form

Document Date:
15 March 2026

VOLUNTARY INFORMED CONSENT FORM

Comparison of the Transversus Fascial Plane Block and the Anterior Quadratus Lumborum Block for Lower Urogenital Surgery in Pediatric Patients

Date: _____

We invite you to participate in the research project entitled "Comparison of the Transversus Fascial Plane Block and the Anterior Quadratus Lumborum Block for Lower Urogenital Surgery in Pediatric Patients," which will be conducted at the Department of Anesthesiology and Reanimation, Cerrahpaşa Faculty of Medicine, Istanbul University-Cerrahpaşa, under the supervision of Prof. Dr. Pınar Kendigelen (**NCT07256899).** Your child will be included in the volunteer participant group of this study. Scientific conclusions will be drawn from the information and data obtained from you and the other participants. Before deciding whether or not to allow your child to participate in this study, it is important that you understand why the research is being conducted, how and by which methods it will be carried out, what will be expected of you, and the potential benefits, risks, and inconveniences associated with participation.

For this reason, it is important that this form be read carefully and fully understood. If there is anything you do not understand or that is unclear to you, please request an explanation. Participation in this research is entirely voluntary. You have the right not to participate in the study or to withdraw after participation. In particular, please obtain information regarding the following matters related to the project:

This study aims to compare two different pain management techniques in children. Our objective is to ensure that your child experiences less pain during and after the surgical procedure. This study will help determine which analgesic method is more effective before, during, and after your child's surgery.

This study will be conducted by anesthesiologists in the Pediatric Surgery operating room over a period of one year. The principal investigator of the study is **Prof. Dr. Ayşe Çiğdem Tütüncü Kayhan,** and the co-investigators are **Prof. Dr. Pınar Kendigelen** and **Lecturer Dr. Münevver Kayhan.**

In our clinic, we frequently use regional anesthetic techniques to ensure that children do not experience pain after surgery, and we are experienced in this field. We now aim to compare two of these techniques. In this study, your child will be randomly assigned to one of two groups. One group will receive a block called the "Anterior Quadratus Lumborum Block," while the other group will receive the "Transversus Fascial Plane Block." These procedures will be performed under ultrasound guidance, and both methods will be applied safely. Both methods are intended to relieve pain and will provide temporary numbness of the nerves in the painful area. Your child will not be placed in a group in which one medication is administered while another is withheld. No group will be left without pain treatment. No patient will be given any harmful medication that may endanger health, nor will any necessary treatment be withheld. Appropriate anesthetic methods will be administered to

every patient independently of this study. No medication harmful to the human body will be used in this study, and no harmful intervention will be performed. You have the right to withdraw from the study at any time. In this study, the block follow-up forms completed for your child and the records related to your child's anesthesia will be kept confidential and will not be shared with any other institution or organization.

No fee of any kind will be requested from you or your child for any procedure to be performed within the scope of this project. This project will not impose any financial burden on your payments related to the Social Security Institution or any other health insurance organizations.

If I permit my child to be included in this research, I believe that the confidentiality of my child's information, which should remain between my physician, my child, and myself, will also be approached with great care and respect during this study. I have been given sufficient assurance that our personal information will be carefully protected when the results of the research are used for educational and scientific purposes. I may withdraw from the study at any time during the conduct of the project without stating any reason. (However, I am aware that, in order not to place the researchers in a difficult position, it would be appropriate to inform them in advance if I intend to withdraw from the study.)

I will not assume any financial responsibility for expenses related to the research. No payment will be made to me.

I have been given the necessary assurance that, should any health problem arise, whether directly or indirectly, for reasons resulting from the research procedures, all necessary medical interventions will be provided. (I will not bear any financial burden related to these medical interventions.)

If I encounter any health problem during the research, I understand that I may contact Dr. Münevver Kayhan at any time at 05057983044, Department of Anesthesiology and Reanimation, Cerrahpaşa Faculty of Medicine.

I am not obliged to participate in this research and may choose not to do so. I have not been subjected to any coercive behavior regarding participation in the research. I also understand that, if I refuse participation, this will not in any way adversely affect my child's medical care or our relationship with the physician.

I confirm that I have understood in detail all the explanations provided to me. After also discussing the matter with my child, who will participate in the study, and after having had sufficient time to consider it, I have decided that my child may take part in the above-mentioned research project as a "participant." I accept this invitation with full willingness and satisfaction. A signed copy of this consent form will be given to me.

Parent or Legal Guardian of the Volunteer

Name and Surname: _____

Signature: _____

Address (and, if available, telephone/fax number): _____

_____

Researcher Providing the Explanations

Name and Surname: _____

Signature: _____

Institutional Staff Member Witnessing the Consent Process from Beginning to End

Name and Surname: _____

Signature: _____

Title/Position: _____