

# Cover Page for ClinicalTrials.gov Posting

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Official Title:

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

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NCT07256899

Document Type:

Protocol (including Ethics Committee Approval & Statistical Analysis Plan)

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# ENGLISH VERSION

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## STUDY PROTOCOL AND ETHICS

This randomized controlled study was conducted in pediatric patients aged 6 months to 12 years undergoing lower abdominal urogenital surgery at Istanbul University-Cerrahpaşa. Ethical approval was obtained from the Institutional Ethics Committee (Approval No: 1452066; Date: 27 October 2025), and the study was registered at ClinicalTrials.gov (NCT07256899). Written informed consent was obtained from all legal guardians.

Patients were randomized into two groups: anterior quadratus lumborum block (QLB) and transversalis fascia plane block (TFPB). Blocks were performed under ultrasound guidance using 0.25% bupivacaine at a dose of 0.4 mL/kg.

Primary outcomes included perioperative pain scores and analgesic consumption. Secondary outcomes included time to first analgesic requirement and patient/parent satisfaction.

## STATISTICAL ANALYSIS

Statistical analyses and visualizations were performed using R software (version 4.4.2). Normality of continuous variables was assessed using histograms and the Shapiro–Wilk test. As normal distribution assumptions were not met, continuous variables were presented as median and interquartile range (IQR), while categorical variables were expressed as frequencies and percentages.

Comparisons between two independent groups (Ant-QLB and TFPB) were performed using the Mann–Whitney U test for continuous variables and Fisher’s Exact test for categorical variables. Repeated measurements of intraoperative hemodynamic parameters (heart rate and mean arterial pressure) and postoperative pain scores were analyzed using linear mixed-effects models, including group, time, and group × time interaction as fixed effects.

Time to first postoperative analgesic requirement (0–8 hours and 0–24 hours) was analyzed using Kaplan–Meier survival analysis and compared using the log-rank test.

The lme4 and lmerTest packages were used for mixed-effects modeling; the survival package was used for survival analysis; and ggplot2 and survminer packages were used for visualization. All tests were two-sided, and  $p < 0.05$  was considered statistically significant.

# TÜRKÇE ORJİNAL

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## İSTATİSTİKSEL ANALİZ

İstatistiksel analizler ve görselleştirmeler R yazılımı (ver. 4.4.2) kullanılarak gerçekleştirildi. Sürekli değişkenlerin normal dağılıma uygunluğu histogramlar ve Shapiro–Wilk testi ile değerlendirildi. Normal dağılım varsayımı sağlanmadığından sürekli değişkenler medyan ve çeyrekler arası aralık (IQR) olarak sunuldu.

İki bağımsız grup arasında karşılaştırmalarda Mann–Whitney U testi ve Fisher’s Exact test kullanıldı. Tekrarlı ölçümler Linear Mixed-Effects Models ile analiz edildi. Sağkalım analizleri Kaplan–Meier ve log-rank test ile gerçekleştirildi. Tüm testler çift yönlü olup  $p < 0.05$  anlamlı kabul edildi.