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Official Title: Thoraco Lumbar Vertebral Length and Bupivacaine Dosage in C-Section

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CLINICAL RESEARCH APPLICATION ETHICAL COMMITEE EVALUATION FORM

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APPLICATION INFO	Name of Research	Vertebral column length-based bupivacaine dosing for spinal anesthesia in cesarean section			
	EUDRACT NUMBER	2025/62			
	Responsible Researcher's Title/Name/Surname	Prof. Dr. Kudret Doğru			
	Responsible Researcher's Expertise Field	Anesthesiology and Reanimation			
	Coordinator's Title/Name/Surname	Prof. Dr. Kudret Doğru			
	Coordinator's Expertise Field	Anesthesiology and Reanimation			
	Research Centre	Anesthesiology and Reanimation Department Erciyes University			
	Research Centre's Address	ERCİYES UNIVERSITY MEDICAL FACULTY			
	Name of Referenced Ethical Instutition	ERCİYES UNIVERSITY MEDICAL FACULTY ETHICS INSTUTION			
	Supporter's Address	-			
	Address of supporter's legal represantative				
	Master Thesis / Academical Purpose	Master Thesis	Academic Purpose		
	Research Phase and Type	Phase 1	------		
		Phase 2	------		
		Phase 3	------		
		Phase 4	x------		
		BE/BY	------		
		OTHER	Individual research project		Define if others:
		Research besides Medicine	------		Explain
	Centers that Contribute to Research	Solecenter x	Multiplecentre	National x	International

	Document name	Date	Version number	Language		
Evaluated Documents	Research Protocol			Turkish x	English	Other
	Research Brochure			Turkish x	English	Other
	Informed Acceptance Form			Turkish x	English	Other
	Data Report Form			Turkish x	English	Other

Evaluated Other Documents	Document Name		Explanation
	Research Budget		
	Insurance		
	Patient Card/Diaries		
	Announcement		
	Yearly Declaration		
	Final Report		
	Security Declarations		

Etical Commitee Evaluation Form

2010.016.140

Decision Information	**Decision No: 2025/62**	**Decision Date:**
	Research ,whose application information ,file and design given above ,which will be carried on by ------ ,who is a Lecturer at University of Erciyes (Kayseri) Faculty of ------ has been examined in terms of its purpose, scope, approach and techniques by the ethical committee and finally ethical committee agreed that mentioned application is ethically suitable to present to deanship.	**05.02.2025**

Prof. Dr. Nuri TUTAR

Chairman of the ethics committee

INFORMED CONSENT FORM (ICF)

You have been invited to participate in a study titled " **Vertebral column length-based bupivacaine dosing for spinal anesthesia in cesarean section.**"

This study is being conducted for research purposes. Before deciding to participate in the study, it is important for you to understand why and how the research is being conducted, how the information about you will be used, what the study entails, and its potential benefits, risks, and discomforts. Please take the time to carefully read the information below and discuss it with your family and/or doctor. After you are fully informed about the study and your questions have been answered, if you wish to participate, you should sign this form of your own free will. Thanks to this research, the mechanism underlying the less frequent observation of a decrease in blood pressure during cesarean surgeries will be determined.

Thus, it will help patients have a more comfortable surgical experience. In this study, no medication or method other than the routine practice at our University hospital will be used. In your cesarean section, spinal anesthesia will be administered as recommended by the World Health Organization. When you arrive in the operating room, your waist-to-neck length will be measured with a tape measure while you are sitting on the operating table. The amount of medication we will administer to numb your waist will be determined based on your height and weight, and the numbing will be performed. Later, when the numbness is fully achieved, your surgery will be allowed. We do not expect any pain or adverse conditions during the measurement. During this procedure, your blood pressure, pulse, oxygen levels, and all vital signs will be routinely monitored. In case of a drop in blood pressure or a decrease in heart rate during spinal anesthesia, necessary medical interventions will be carried out without delay. You will be taken to the Maternity Clinic after your surgery.

For any medical situation, you can call Prof. Dr. Kudret Doğru at 05334735112, available 24/7.
Section on Informed Consent: "I have read all the explanations in the Informed Consent

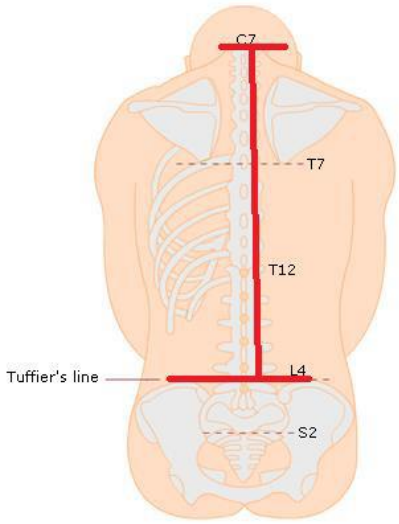
Form." I received written and verbal explanations of the research, including its subject and purpose, from the physician listed below. I understand that I am voluntarily participating in the study, that I can withdraw from the study at any time with or without justification, and that I can be excluded from the study by the researcher regardless of my own will. I agree to participate in the said research of my own free will, without any pressure or coercion."

Volunteer Name: …….Surname:……

Date Signature:

Study Protocol

In the study, an observational clinical study strategy will be followed in routine spinal anesthesia applications. Applications will be made to the Erciyes University Ethics Committee. Patients will be informed before the procedure begins, and their written consent will be obtained. The study will be conducted from May 2025 to December 2025. ASA III and IV, preeclampsia, cardiorespiratory problems, pregnancy or pre-existing diabetes, intrauterine growth restriction, and fetal abnormalities, abruptio placentae, placenta previa, placenta accreta or percreta, pregnant women who are in an emergency situation and unwilling to participate, those with contraindications to spinal anesthesia, those weighing <50 kg or >110 kg, and those taller than 170 cm or shorter than 150 cm will not be included in the study. There was no pre-planning among the patients. The patient will undergo standard monitoring, including non-invasive blood pressure, ECG, and pulse oximetry, with baseline blood pressure and heart rate measurements recorded. Two 20-G intravenous cannulas will be inserted, and an IV balanced solution will be administered using these routes. Vertebral body length (VBL) measurements are determined by measuring from the midpoint of C7 to the Tuffier line. To test this hypothesis, a 0.5% heavy bupivacaine dose will be calculated as 0.2 mg x (vertebral body length = distance between C7 and Tuffier's line) cm. In our clinic, all three dose calculation systems are routinely used in spinal anesthesia for cesarean sections. As is routinely done, after skin infiltration with lidocaine, a 25-G short bevel Quincke spinal needle will be inserted into the L3-4 vertebral space while the patient is in a sitting position. After cerebrospinal fluid aspiration, the calculated dose of bupivacaine will be administered over 5 seconds. The patient and evaluator group assignments will be unknown. The data of 285 patients who underwent routine procedures will be examined, and the results will be separated based on the dose of bupivacaine administered to the pregnant woman. According to the results, the data is as follows: Patients in the VBU Group (thoracolumbar vertebral length between C7 and the Tuffier line) received 0.2 mg x VBU cm of 0.5% hyperbaric bupivacaine, while patients in the Height Group (calculated dose) received a volume of 0.5% hyperbaric bupivacaine based on a height-adjusted dose of 0.065 mg/cm height, calculated according to the patient's height. The AD Group (adjusted dosage) will receive intrathecal heavy bupivacaine (0.5%) as determined by Harten's dosage chart, adjusted for the patient's height and weight (Table 1) [11].



Postoperative analgesia will be performed bilaterally with a transverse abdominis plane block using 20 ml of 0.25% bupivacaine. The upper sensory level of anesthesia will be systematically assessed by measuring the loss of needle-prick sensation in the midclavicular line at 2-minute intervals. Additionally, the time to surgical incision, the sensory block level at the thirty-minute mark, the performance of the head-down tilt, the administration of additional analgesia, and the transition to general anesthesia will be recorded. Mean arterial blood pressure and heart rate will be recorded initially and then at 3-minute intervals starting 3 minutes after spinal injection and continuing until the end of the surgical procedures. The onset of nausea and vomiting will be systematically recorded along with the amount of ephedrine administered. A nurse present during delivery who is unaware of the patient's assigned group will assess the Apgar scores both 1 minute

Clinical Management

As per routine practice, patients will be immediately placed in the supine position with a 15-degree left lateral tilt. All patients will receive supplemental oxygen via a nasal cannula. Bradycardia (defined as a heart rate < 60 beats/min) will be treated with 0.5 mg of intravenous atropine. Hypotension, defined as a decrease in baseline systolic blood pressure of more than 30% or a systolic blood pressure below 90 mmHg, will be managed with 5 mg of intravenous ephedrine. In instances of dizziness, nausea, or vomiting, 5 mg of ephedrine will also be administered. Routine prophylaxis will be applied to prevent nausea and vomiting. Surgical incision will be permitted once the loss of pinprick sensation is confirmed bilaterally at the T6 dermatome. If patients experience discomfort during the procedure, a bolus of 0.5 mg/kg propofol and 0.25 mg/kg ketamine will be administered intravenously, consistent with routine practice. If these measures prove ineffective, the patient will be transitioned to general anesthesia and excluded from the study.

Following delivery, 100 IU of carbetocin will be administered as a uterotonic via graduated intravenous infusion. At the end of the procedure, 1000 mg of IV paracetamol will be administered for analgesic purposes. Supplemental postoperative analgesia will be provided via a bilateral transversus abdominis plane (TAP) block using 20 ml of 0.25% bupivacaine.

Monitoring and Data Collection

The upper sensory level of anesthesia will be systematically assessed every two minutes along the midclavicular line using the loss of pinprick sensation. Additionally, the time to surgical incision, the sensory block level at the 30-minute mark, the application of Trendelenburg positioning, the administration of supplemental analgesia, and any transitions to general anesthesia will be recorded. Mean arterial pressure (MAP) and heart rate will be recorded at baseline and every 3 minutes thereafter, beginning 3 minutes after the spinal injection and continuing until the end of the surgical procedure. The occurrence of nausea and vomiting, along with the total amount of ephedrine administered, will be systematically documented. An attending nurse, blinded to the patients' group assignments, will assess Apgar scores at both 1 and 5 minutes post-delivery.

Statistical Analysis

A pre-study power analysis was performed using G*Power (v3.1.9.7; Franz Faul, Universität Kiel, Germany) based on the primary hypothesis defined as the rate of hypotension in each group. Using data from retrospective studies and assuming an effect size of 0.30, it was calculated that at least 69 patients per group (207 total) were required for an ANOVA test. This calculation provides a study power of 0.95 with a significance level (α) of 0.05.

Data will be analyzed using Analysis of Variance (ANOVA), the Kruskal-Wallis test, and Fisher's exact test, as appropriate. Bonferroni corrections will be applied for multiple comparisons. A p-value < 0.05 will be considered statistically significant. All statistical analyses will be performed using JAMOVI version 2.6.19 for Windows.

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