TITLE PAGE

Name Of The Study: Investigation of the effects of rhomboid intercostal block on acute postoperative pain management and chronic pain prevalence in patients undergoing breast surgery

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INFORMED CONSENT FORM

Investigation of the effects of rhomboid intercostal block on acute postoperative pain management and chronic pain prevalence in patients undergoing breast surgery	
VOLUNTEER INITIALS:	
VOLUNTEER NUMBER	

""You are being invited to participate in a scientific study. Before making your decision, it is important that you fully understand what will be done in this study and why. Please read the following explanations carefully; if you wish, discuss them with your friends, family and physician. If there is anything unclear or you would like further clarification, ask us. Think carefully before deciding whether to participate in this study..

1. **What is the purpose of this study?**

Rhomboid Intercostal Block (RIB) is a regional anesthesia technique. RIB is applied by administering local anesthetic medication between your back muscles with the help of a needle and is an effective method for providing pain control in patients undergoing breast surgery. Regional anesthesia methods prevent the perception and spread of pain by anesthetizing the nerves that cause pain in the surgical area before they reach that area, and is an area where current anesthesia research is focused. These methods have been shown to reduce postoperative pain levels, reduce the consumption of painkillers and the side effects of painkillers. Rhomboid intercostal block has been proven effective in the first 24 hours after surgery in patients undergoing breast surgery, but its effect on long-term pain has not been studied. In this study, the presence of chronic pain and painkiller needs of patients undergoing breast surgery will be evaluated at the end of 3 months. Both methods are effective and widely used methods in providing pain control. Your pain will be monitored more closely when you participate in the study. We will check your pain and general condition with frequent visits, especially on the first day. Any surgical pain that may occur will be effectively treated with a pain pump applied intravenously in both groups, and additional medication will be administered if necessary. Which method will be applied to the patients will be determined randomly. Randomization is the process of distributing volunteers to groups in an unbiased manner with a computer-aided application in order to reduce bias. Our aim is to see the effect of the applied block on the presence of pain in the third month.

2. How will the study drug be used? Where and how should I store the drug?

This is not a drug study. Local anesthetic will be applied between the muscles in your back by the anesthesiologist in the operating room environment.

3. **What will be done to me?**

Local anesthetic will be administered to your back with a needle with the help of ultrasound and the nerve will be numbed. This nerve numbing will be applied to the side where you will have breast surgery (right, left or both).

4. **If I participate in this study, what do I need to do?**

You do not need to do anything. You will be called by us in the third month following your surgery and asked to participate in a short survey about your pain.

5. **How long will the study last and how many volunteers will participate?**

The study will last 12 months in total and 90 patients will be included in the study. You are expected to participate in the study by phone call for 24 hours from the time of your surgery and once every 3 months.

6. **Are there any side effects of the procedures and medications used in this study? What will happen if I develop these side effects?**

No special side effects are expected depending on the procedure we apply.

7. **Who will cover the costs of tests, examinations, medications, etc. arising from my participation in the study? Will I have to pay?**

No expenses arising from the study will be incurred by you or your social security institution.

8. **Will the volunteers participating in the study be insured?** No
9. **Will my participation in this study, my medical and personal information be kept confidential? Who will see this information?**

Records that will reveal your identity will be kept confidential and will not be disclosed to the public. Your identity will remain confidential even if the research results are published. Your information will be seen by the responsible and assistant researchers.

10. **Will this study be approved by an official authority?**

Yes. It will be approved by the Koç University Clinical Research Ethics Board.

11. **Who can I contact if I want more information or if there is an emergency?**

"You can contact your doctor for more information about the study and any side effects that may occur during treatment.

For information, you can contact Dr. Belitsu SALGIN directly or call 08502508250 (ext. 23849).

(Declaration of Participant/Patient)

It was stated that a medical research would be conducted in the Department of Anesthesiology and Reanimation of Koç University Faculty of Medicine and the above information regarding this research was conveyed to me. After this information, I was invited to such a research as a "participant". I believe that if I participate in this research, the

confidentiality of my information, which should remain between me and the physician, will be treated with great care and respect during this research. I have been given sufficient confidence that my personal information will be meticulously protected during the use of the research results for educational and scientific purposes. I may withdraw from the research without giving any reason during the implementation of the project. (However, I am aware that it would be appropriate to notify the researchers in advance that I will withdraw from the research in order not to put them in a difficult situation.) In addition, I may be excluded from the research by the researcher provided that no harm is done to my medical condition. I do not assume any financial responsibility regarding the expenses to be made for the research. I will not be paid either. The necessary assurance was given that any health problem that may arise due to reasons arising from the research application, whether directly or indirectly, will be provided with all kinds of medical intervention. (I will not be financially burdened with these medical interventions). I am not obliged to participate in this research and I may choose not to participate. I have not been subjected to any coercive behavior regarding my participation in the research. I also know that if I refuse to participate, this will not harm my medical care or my relationship with the physician. I have understood all the explanations given to me in detail. After a period of self-reflection, I have decided to take part in this research project as a “participant” (subject). I accept this invitation with great pleasure and voluntarily. A copy of this signed form will be given to me.

Participant:	**Researcher:**	**Witness:**
Name, Surname:	Name, Surname :	Name, Surname:
Address:	Address:	Address:
Tel.:	Tel.:	Tel.:
Signature:	Signature:	Signature: