



AFYONKARAHİSAR HEALTH SCIENCES UNIVERSITY CLINICAL RESEARCH ETHICS BOARD

INFORMED VOLUNTARY CONSENT FORM

Document Date (Last Updated and Ethics Approved): 24 August 2021

Document Code: EPK. FR.04

Publication Date:
23.11.2013

Revision Date: 25.06.2013

Revision No: 02

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PLEASE READ THIS DOCUMENT CAREFULLY

Project name: Effect of Bilateral Lumbar Erector Spinae Plane Block on Postoperative Analgesia in Lumbar Spinal Surgery

Dear

You are invited to participate in a study conducted at Afyon Health Sciences University titled "**The Effect of Bilateral Lumbar Erector Spinae Plane Block on Postoperative Analgesia in Lumbar Spinal Surgery.**" Before deciding whether to participate, you should fully understand the purpose, procedures, possible benefits, risks, and discomforts of the study. Please read this form carefully. You may discuss it with your family or physician. If you have questions, please ask. If you agree to participate, you will receive a signed copy of this form.

Participation in this research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits. All data collected will remain confidential and used only for scientific purposes.

The information obtained from this study will be used solely for research purposes and your identity will be kept strictly confidential.

You have the right to refuse participation or to withdraw from the study at any time. In either case, there will be no penalty or loss of any benefits to which you are entitled.

Principal Investigator: Prof. Dr. Remziye SIVACI

Afyonkarahisar Health Sciences University

Department of Anesthesiology and Reanimation

Note:

The publication date (23.11.2013) and revision date (25.06.2013) refer solely to the standard institutional informed consent form template of Afyonkarahisar Health Sciences University.

This informed consent form was approved by the local ethics committee and last updated for use in this study on **24 August 2021**.

Volunteer's Name— Surname / Date / Signature		Name-Surname of the Researcher Providing The Information Date / Signature	
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T.C. Sağlık Bakanlığı
Türkçe Kamu
Hastaneleri Kurumu

AFYONKARAHİSAR HEALTH SCIENCES UNIVERSITY CLINICAL RESEARCH ETHICS BOARD

INFORMED VOLUNTARY CONSENT FORM 24.08.2021

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Purpose of the Study:

Our study is a **clinical research** project. The aim of this study is to investigate the effects of the lumbar erector spinae plane (ESP) block—which we routinely perform in patients undergoing lumbar spinal surgery—on postoperative pain control, the amount of analgesics (pain medications) used, postoperative early mobilization (first standing/physiotherapy) and the length of hospital stay.

Study Location(s):

Afyonkarahisar Health Sciences University Hospital

Researchers Participating in the Study:

Prof. Dr. Remziye Gül SIVACI / Department of Anesthesiology and Reanimation

Research Assistant Dr. Merve KAYNAK / Department of Anesthesiology and Reanimation

Lecturer Dr. Serhat YILDIZHAN / Department of Neurosurgery

Duration of the Study: 8 months

Expected Number of Participants: 80

Potential Benefits of Participating in the Study:

Participation in this study is entirely voluntary. You may refuse to take part or withdraw at any stage, and your future medical care will still be guaranteed. The lumbar erector spinae plane (ESP) block is a routine technique we use in surgeries such as lumbar disc herniation and spondylolisthesis operations. These anesthesia methods help delay the onset of postoperative pain and reduce the amount of pain you experience after surgery.

Risks Associated With Participation in the Study:

- Temporary nerve symptoms
- Local anesthetic intoxication

Volunteer's Name— Surname / Date / Signature		Name-Surname of the Researcher Providing The Information Date / Signature	
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- Infection
- Pain or discomfort during needle insertion

These risks are uncommon, generally mild, and typically resolve with appropriate and timely medical management.

 T.C. Sağlık Bakanlığı <small>Türkiye Kamu Hastaneleri Kurumu</small>	AFYONKARAHİSAR HEALTH SCIENCES UNIVERSITY CLINICAL RESEARCH ETHICS BOARD			
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I, [name and surname of the volunteer (in their own handwriting)], have read the text above. I fully understand the scope and purpose of the study I am being asked to participate in, as well as the responsibilities I will undertake as a volunteer. I have had the opportunity to ask questions and discuss the study, and I have received satisfactory answers. The possible risks and benefits of the study have also been explained to me verbally. I understand that I may withdraw from this study at any time and without providing any reason, and that my current treatment will not be negatively affected if I choose to withdraw.

Under these conditions:

1. I voluntarily agree to participate in this research (or for my child/ward to participate) without any pressure or coercion.
2. I consent to my personal information being accessed by the individuals/institutions/organizations authorized by applicable regulations, if needed.
3. I consent to the information obtained in the study being used for scientific publication, archived, and transferred abroad if necessary.

NOTE: One copy of this form will be kept by the volunteer, and the other copy will be placed in the patient file. For healthy volunteers who do not have a patient file or protocol number, a copy of the consent form must be kept by the principal investigator.

Contact Person(s):

(Names and phone numbers of the individuals to be contacted for information about the study or in case of any adverse event)

Research Assistant Dr. Merve KAYNAK – 05069656686

Principal Investigator: Prof. Dr. Remziye SIVACI – 05052371291

Volunteer's Name– Surname / Date / Signature		Name-Surname of the Researcher Providing The Information Date / Signature	
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