“Efficacy of Ultrasound-Guided Retrolaminar Block Combined With Standard Multimodal Analgesia for Postoperative Pain Management in Lumbar Spine Surgery: A Randomized Controlled Trial”

Informed Consent Index:

Clínica Universidad de los Andes

INFORMED CONSENT

Ultrasound-guided retrolaminar block as analgesia for lumbar spine surgery: a randomized clinical trial

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Service or Department: Anesthesiology
Sponsor Information: NOT APPLICABLE

The purpose of this document is to provide you with all the necessary information so that you can decide whether or not you wish to participate in this research project. If you wish, you may consult with a family member or friend regarding this decision. You have been invited to participate because **you meet the inclusion criteria for the project as you are undergoing lumbar spine surgery.**

Introduction: Lumbar spine surgery produces moderate to severe pain in the postoperative period for patients. Multiple analgesic schemes have been attempted to manage this pain and decrease the hospital stay of patients. However, little has been studied regarding "regional blocks," which correspond to infiltrations of standard local anesthetic (Levobupivacaine), under ultrasound guidance, adjacent to the vertebrae to be operated on. These are a good and safe analgesic alternative for the postoperative period of these patients. In this case, we will perform an infiltration called in the literature "Retrolaminar Block". We believe that infiltrating this local anesthetic, under ultrasound guidance, in patients under general anesthesia, before the start of surgery, could decrease the consumption of opioid analgesic medications (morphine family), decrease postoperative pain, and accelerate hospital discharge.

Objectives: The objectives of this research are to **compare the analgesic efficacy, postoperative morphine consumption, and safety of the retrolaminar block versus standard analgesia in patients undergoing lumbar spine surgery of 3 or fewer levels.** The study will include a total number of **50** subjects, from 1 health center: Clínica Universidad de los Andes.

Procedures: If you accept to participate, you will be subjected, for a period of **72 hours**, to the following procedures: randomization to receive the following anesthesia and analgesia:

Intervention Group: General anesthesia and standard analgesia (Intravenous Paracetamol and anti-inflammatories) + Preoperative ultrasound-guided Retrolaminar Block + *Patient Controlled Analgesia* (PCA) pump with postoperative morphine, with which you will have a button to self-administer intravenous Morphine in a dose of 1 mg, in case of presenting moderate to severe pain.

Control Group: General anesthesia and standard analgesia (Intravenous Paracetamol and anti-inflammatories) + *Patient Controlled Analgesia* (PCA) pump with postoperative morphine, with the which you will have a button to self-administer intravenous Morphine in a dose of 1 mg, in case of presenting moderate to severe pain. **NO** regional anesthesia block under ultrasound will be performed.

Later, you will be visited by anesthesiologists and nurses from the pain team to **ask you for your pain score between 0 and 10 points, at 0, 6, 12, 24, 48, and 72 hours post-surgery. Additionally, your total Morphine consumption during your hospitalization via the previously described PCA pump**

will be verified.

Also, in case of need, we will access your electronic medical record to search for any data regarding your postoperative pain or adverse effects of morphine use.

Benefits: In addition to the benefit that this study will signify for the progress of knowledge and the better treatment of future patients, your participation in this study will bring you the following benefits: **exclusive follow-up by the anesthesiology and pain team, to optimize your postoperative analgesic management.**

Risks: The application of a retrolaminar block with local anesthetics may be accompanied by the following unwanted effects: infection at the puncture site, bleeding at the puncture site, or intoxication by local anesthetics (1.8 out of every 1,000 patients). Any other effect that you consider may derive from the application of this analgesic technique must be communicated to the Pain Team of Clínica Universidad de los Andes, at the phone number +56977313750.

The researchers will assume responsibility for damages produced specifically by your participation in the study.

Costs: The medications, supplies, or techniques under study: Bilateral retrolaminar block under ultrasound guidance with Levobupivacaine (local anesthetic commonly used in clinical practice) will be provided by Clínica Universidad de los Andes, without any additional cost to you during the development of this project. The study does not require extraordinary exams or services, distinct from the usual practice performed in the operating room.

Compensation: You will not receive any financial compensation for your participation in the study.

Confidentiality: All information derived from your participation in this study will be preserved under strict confidentiality, which excludes access by researchers or research supervisory agencies. Any publication or scientific communication of the research results will not include information that allows identifying your participation in the study.

Voluntariness: Your participation in this research is totally voluntary and you may withdraw at any time by communicating this to the investigator and your treating physician, without this signifying modifications to the study and habitual treatment of your illness. Likewise, your treating physician or the investigator may determine your withdrawal from the study if they consider that this decision is in your benefit.

Conclusion: *"I have understood the information in this document and I have clarified all my doubts, therefore, I grant my free and voluntary consent to participate in this project".*

You will receive a signed copy of this document. If you require any other information regarding your participation in this study, you may communicate with:

Investigator: Dr. Roberto Coloma Díaz +56977313750

In case of doubt regarding your rights, communicate with the Scientific-Ethical Committee of the Universidad de los Andes, Dr. Duniel Ortuño Borroto, phone: +56 2 2618 2154, mail: cec@uandes.cl, located at Av. Mons. Álvaro del Portillo 12455, Las Condes, Santiago.

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Name of Subject	Signature	Date and Time
RUN: _____		
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Name of Investigator	Signature	Date and Time
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Name of Director/Rep. of Establishment	Signature	Date and Time
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