Informed Consent Form (ICF)
Opioid-Free vs Opioid-Based Anesthesia in Bariatric Surgery

NCT Number: NCTXXXXXXXX

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1. Study Title

Opioid-Free Anesthesia vs Opioid-Based Anesthesia in Laparoscopic Bariatric Surgery

Principal Investigators:

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- Fábio Almeida, MD, Anesthesiologist

Hospital Lusíadas Amadora – Lusíadas Saúde, S.A.

2. Invitation to Participate

You are being invited to participate as a volunteer in a clinical research study comparing two anesthesia techniques used during bariatric surgery. Before you decide, it is important that you understand why the research is being done and what it involves.

3. Purpose of the Study

The purpose of this study is to evaluate whether opioid-free anesthesia (OFA) provides benefits compared to opioid-based anesthesia (OBA) in terms of postoperative pain control, nausea and vomiting (PONV), complications, length of hospital stay, and overall patient satisfaction.

4. Procedures Involved

If you agree to participate:

- Your anesthetic technique will be assigned randomly to OFA or OBA.

- Clinical and demographic data will be collected perioperatively.

- Your postoperative recovery will be monitored until discharge.

All procedures are part of standard clinical practice. No experimental drug is being tested.

5. Risks and Discomforts

Both anesthesia techniques are widely used and considered safe. Possible risks include nausea, vomiting, drowsiness, dizziness, changes in blood pressure or heart rate, allergic reactions, pain, or discomfort. Rare but serious complications may occur. These risks will be monitored closely by the clinical team.

6. Benefits

You may or may not directly benefit. However, your participation may help improve anesthesia practices for future patients.

7. Alternatives to Participation

Participation is optional. If you choose not to participate, you will receive the usual standard of anesthetic care, with no impact on your treatment.

8. Confidentiality and Data Protection (GDPR)

Your personal information will be collected only for study purposes, stored securely, accessed only by investigators, and kept for the minimum period required by law. Your data will be anonymized for analysis and publication.

Your name will NOT appear in any document, dataset, or publication.

Under GDPR, you have the right to access, correct, withdraw consent, or request deletion of your data when legally applicable.

9. Costs and Compensation

Participation does not involve additional costs. You will not receive financial compensation, nor will you be charged for participating.

10. Voluntary Participation and Right to Withdraw

Participation is entirely voluntary. You may withdraw at any time without penalty, loss of benefits, or impact on your care.

11. Ethics Approval

This study has been reviewed and approved by the Ethics Committee of Hospital Lusíadas Amadora.

12. Contacts for Questions

If you have questions, concerns, or wish to withdraw, please contact:

Emanuel Almeida, MD – Anesthesiologist

Hospital Lusíadas Amadora

Phone: +351963502309

Email: emanueljoao7@gmail.com

13. Statement of Consent

I, _____, have read (or had read to me) the information in this document. I have had the opportunity to ask questions and all have been answered to my satisfaction. I understand that participation is voluntary and that I may withdraw at any time. I voluntarily agree to participate and authorize the use and publication of my data for this research purpose only.

Participant Signature: _____

Date: _____

14. Statement of the Investigator Obtaining Consent

This study has been fully explained to the participant or caregiver. Sufficient information has been provided to allow an informed decision.

Principal Investigator Signature: _____

Date: _____