

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

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Title

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

Version

1.0

Principal Investigator

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1. Background and Rationale

Obesity is a chronic disease commonly associated with complications. Bariatric surgery is effective, but pain and PONV remain challenges. Opioid-free anesthesia (OFA) may reduce opioid-related adverse effects. This trial compares OFA vs. OBA in laparoscopic bariatric surgery.

2. Objectives

Primary: Compare postoperative pain (NRS) between OFA and OBA.

Secondary: NOL index; rescue analgesia; opioid consumption; PONV; satisfaction; complications; LOS.

3. Study Design

Interventional, prospective, randomized, parallel-group clinical trial.

Allocation: Randomized

Masking: None (open-label)

Arms: 2

Primary Purpose: Treatment

Phase: Not applicable

4. Study Arms and Interventions

Arm 1 – OBA: Remifentanil infusion; propofol; rocuronium; desflurane; dexamethasone; cefazolin; esomeprazole; postoperative multimodal analgesia; rescue opioids.

Arm 2 – OFA: Dexmedetomidine bolus + infusion with ketamine and lidocaine; propofol; rocuronium; desflurane; postoperative opioid-free analgesia; rescue tramadol.

5. Eligibility Criteria

Inclusion: Adults ≥ 18 years; BMI ≥ 35 with comorbidities or ≥ 40 ; elective laparoscopic bariatric surgery; consent.

Exclusion: Pregnancy; substance abuse; severe psychiatric disease; contraindication to study drugs.

6. Outcomes

Primary: Postoperative pain (NRS) at PACU arrival, PACU discharge, 24h, discharge.

Secondary: NOL index; rescue analgesia; opioid consumption; PONV; satisfaction; complications; LOS.

7. Sample Size

60 participants (30 per arm). Convenience sample based on feasibility.

8. Randomization

Computer-generated 1:1 allocation.

9. Blinding

None (open-label).

10. Data Collection

NRS, PONV, rescue analgesia, satisfaction, complications; NOL intraoperative at multiple time points.

11. Statistical Analysis

Shapiro-Wilk; t-test; Mann-Whitney; chi-square; GLM with Bonferroni; significance $p < 0.05$.

12. Ethical Considerations

Approved by the Ethics Committee of Hospital Lusíadas Amadora. Written informed consent obtained.

13. Data Management

Password-protected storage. No IPD sharing.

14. Dissemination Plan

Results will be published in peer-reviewed journals.

15. Timeline

Start, end, and completion dates to be added.