STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official Study Title:

Comparison of pain relief by bupivacaine with dexmedetomidine and bupivacaine alone in transversus abdominis plane block for postoperative analgesia in patients undergoing abdominal surgeries

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Sponsor / Institution:

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Study Synopsis

Introduction

This future study aims to evaluate the efficacy of combining bupivacaine with dexmedetomidine for post-operative analgesia, compared to bupivacaine alone, in patients undergoing abdominal surgery. The methodology will follow Flick's (2015) research framework, ensuring rigorous data collection and thorough analysis. This research will focus on evaluating pain relief and safety outcomes for post-surgical patients.

Research Philosophy

The study will adopt a **positivist perspective**, focusing on objective data collection and unbiased analysis. This approach aims to minimize researcher bias, as discussed by Park et al. (2020) and Corry et al. (2019), ensuring the objectivity of the medical outcomes. While this approach limits context-dependent insights, it will ensure that results are impartial, particularly in the management of post-surgical pain, as proposed by Ryan (2018).

Research Design

The study will use a **quantitative research design**, in alignment with the positivist approach, prioritizing numerical data and statistical analysis (Queiros et al., 2017). This design will allow for broader generalizations and has been validated for its reliability and replicability, ensuring that findings will be applicable to future similar studies.

Study Design

A **Randomized Controlled Trial (RCT)** design will be employed, following the **CONSORT guidelines** to reduce bias through random selection and allocation of treatments (CONSORT, 2017). This randomized design will ensure the validity and reliability of the study results.

Study Site and Duration

The study will take place at **Sheikh Zayed Medical College and Hospital**, Rahim Yar Khan, selected for its accessibility and the researcher's familiarity with the institution. The trial will span **four months**, which will be sufficient for data collection, including baseline measurements and post-operative assessments.

Data Collection

Primary data collection will be utilized, focusing on direct clinical data to ensure the study's medical relevance. As noted by Hariton and Lucascio (2018), primary data improves the effectiveness of medical research. Key data points will include heart rate, mean arterial pressure, Visual Analogue Scale (VAS), and sedation levels, measured at various intervals post-surgery.

Sampling

The study will use **non-probabilistic consecutive sampling**, with patients selected based on

specific inclusion and exclusion criteria. Participants will be randomly assigned to two groups using a lottery method, minimizing researcher bias. The sample size will be calculated using VAS ratings, targeting **80 participants**.

Methodology (Data Collection Procedure)

Once ethical approval is obtained, volunteers will be recruited from the **Anesthesia Department** for elective surgeries. Standard pre-operative monitoring will be implemented, and a **TAP block** will be administered using either bupivacaine with dexmedetomidine or bupivacaine alone. Post-operative follow-up will involve assessing pain, sedation, and adverse effects at predetermined intervals.

Data Analysis

Data analysis will be conducted using **SPSS v23** to assess correlations and differences among variables. **T-tests** will be used to evaluate the significance of changes in pain (VAS), heart rate, and secondary outcomes. **Chi-square tests** will be used for categorical data, and **stratification** will control for potential confounders.

Ethical Considerations

Ethical approval will be obtained, and **informed consent** will be secured from all participants, ensuring they fully understand the study procedures. Participant confidentiality will be maintained through data coding, and all medical procedures will adhere to ethical guidelines to safeguard the participants' safety and welfare.