**Study Protocol**

**Preoperative Psychotherapy and Its Effects on Anxiety, Hemodynamics, and Pain in Living Kidney Donors (PREPSY-KD)**

**Protocol Version:** 1.0
**Protocol Date:** November 2023
**Organization's Protocol ID:** KAEK-840

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## 1. Background and Rationale

Living kidney donation is an essential treatment modality for end-stage renal disease (ESRD). Donor nephrectomy, while performed in healthy individuals, is associated with significant psychological stress due to hospitalization, surgical anticipation, anesthesia concerns, and uncertainty regarding recovery. Preoperative anxiety has been shown to negatively affect postoperative pain, hemodynamic stability, anesthetic requirements, and overall recovery.

Psychotherapeutic interventions such as psychoeducation, guided imagery, and diaphragmatic breathing exercises have demonstrated benefits in reducing perioperative anxiety and improving physiological parameters. However, there is limited prospective evidence evaluating the effect of structured preoperative psychiatric consultations on anxiety, hemodynamic responses, and postoperative pain in living kidney donors.

This study aims to assess whether a brief standardized psychiatric consultation administered before donor nephrectomy affects perioperative anxiety levels, intraoperative hemodynamics, and postoperative pain outcomes.

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## 2. Study Objectives

### Primary Objective

- To evaluate the effect of preoperative psychiatric consultation on postoperative pain scores measured via the Visual Analog Scale (VAS) at predefined postoperative time points.

### Secondary Objectives

- To compare preoperative and postoperative anxiety levels between intervention and control groups using the Beck Anxiety Inventory (BAI).
- To compare intraoperative hemodynamic parameters (heart rate, systolic and diastolic blood pressure, $SpO_2$) between groups.
- To evaluate postoperative oxygen saturation trends.
- To assess postoperative opioid consumption and antiemetic requirements.

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## 3. Study Design

- **Study Type:** Interventional

- **Design:** Prospective, randomized, parallel-assignment clinical trial
- **Number of Arms:** 2 (Intervention vs. Standard Care)
- **Masking:** Single-blind (Outcomes Assessor)
- **Allocation:** Randomized
- **Primary Purpose:** Supportive Care
- **Study Duration:** November 2023 – November 2024

Randomization was performed via sealed envelopes during preoperative evaluation. Outcome assessors evaluating VAS scores were blinded to group allocation.

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**4. Study Population**

**Inclusion Criteria**

- Age ≥ 18 years
- ASA physical status I–II
- Voluntary participation with signed informed consent
- Living kidney donor scheduled for elective donor nephrectomy

**Exclusion Criteria**

- Diabetes mellitus diagnosis
- Development of postoperative delirium
- Known psychiatric illness or psychiatric medication use
- Neurological or musculoskeletal disorders
- Chronic pain or chronic pain treatment
- Recent significant psychological trauma
- Analgesic drug use within the last month

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**5. Interventions**

**Intervention Group: Preoperative Psychiatric Consultation**

Participants received a standardized 15-minute psychiatric session one hour before surgery under psychiatrist supervision, including:

- History-taking (3–5 minutes)
- Psychoeducation regarding anxiety and surgical preparation (3–5 minutes)
- Diaphragmatic breathing exercises (1–3 minutes)
- Guided imagery techniques (3–5 minutes)

The intervention was delivered by an anesthesiologist trained by a psychiatrist through structured educational sessions.

**Control Group: Standard Preoperative Care**

Participants received routine preoperative evaluation. No psychiatric intervention was performed.

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**6. Outcome Measures**

**Primary Outcome**

- **Postoperative Pain Score (VAS 0–10)**
  Time Frame: Postoperative 30 minutes, 2 hours, 6 hours, 12 hours, 24 hours, and 48 hours.

**Secondary Outcomes**

1. **State Anxiety Score (Beck Anxiety Inventory, 0–63)**
   Time Frame: 30 minutes preoperatively, postoperative 24 hours, postoperative 48 hours.
2. **Postoperative $SpO_2$ Levels (%)**
   Time Frame: Postoperative 30 minutes, 2 hours, 6 hours, 12 hours, 24 hours, 48 hours.
3. **Intraoperative Heart Rate (beats/min)**
   Time Frame: Pre-induction, 30 minutes after induction, 1 hour after induction.
4. **Intraoperative $SpO_2$ Levels (%)**
   Time Frame: Pre-induction, 30 minutes after induction, 1 hour after induction.
5. **Intraoperative Systolic Blood Pressure (mmHg)**
   Time Frame: Pre-induction, 30 minutes after induction, 1 hour after induction.
6. **Intraoperative Diastolic Blood Pressure (mmHg)**
   Time Frame: Pre-induction, 30 minutes after induction, 1 hour after induction.
7. **Total Opioid Consumption (mg)**
   Time Frame: Intraoperative period and postoperative first 24 hours.
8. **Antiemetic Use (Yes/No, mg)**
   Time Frame: Intraoperative period and postoperative first 6 hours.

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**7. Data Collection Procedures**

Data will be collected at standardized time points by trained staff members. Hemodynamic parameters will be retrieved from anesthesia monitoring records. Pain scores will be evaluated using a 10 cm Visual Analog Scale. Anxiety assessments will be performed by a blinded outcomes assessor.

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**8. Statistical Analysis Plan**

- Categorical variables: $\chi^2$ or Fisher's exact test
- Continuous variables with normal distribution: Independent samples t-test
- Non-normal distribution: Mann–Whitney U test
- Repeated measurements: Repeated Measures ANOVA or Friedman test
- Correlations: Pearson or Spearman coefficients
- Significance threshold: $p < 0.05$
- Software: SPSS 15.0 version

All analyses will be performed per-protocol.

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**9. Ethical Considerations**

- Ethics Committee Approval: **Akdeniz University Clinical Research Ethics Committee** Approval Number: **2023-KAEK-20 / 840**
- Board Status: Approved
- Participation is voluntary; written informed consent obtained from all donors.
- No investigational drug or device used.
- Risks are minimal and limited to standard perioperative care.

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**10. Study Timeline**

- Start of enrollment: November 1, 2023
- Primary completion: October 1, 2024
- Study completion: November 1, 2024

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**11. Data Management and Monitoring**

A formal Data Monitoring Committee is not required due to minimal-risk behavioral intervention and absence of investigational medicinal products.

All data will be anonymized and stored securely following institutional data protection guidelines.

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**12. Publication Plan**

Findings will be submitted to peer-reviewed anesthesiology and transplant journals and may be presented at national and international conferences.

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## 13. References


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