Study Design & Statistical Analysis Plan (SAP)

Study Design

This study is a **multi-center, prospective, randomized controlled trial (RCT)** designed to assess whether **surgical positioning** affects **stone-free rates** and **postoperative complications** in patients undergoing **retrograde intrarenal surgery (RIRS)** for kidney stones.

Randomization and Groups

- **Total Participants:** 128 (based on power analysis)

- **Randomization Ratio:** 1:1

- **Intervention Arms:**

  - **Standard Supine Position Group (n=58)**

  - **T-Tilt Position Group (n=58)** (30° Trendelenburg + 30° elevated surgical side)

Primary and Secondary Outcomes

- **Primary Outcome:**

  - **Stone-free rate at 6 weeks postoperatively**, defined as **residual fragments ≤4 mm on non-contrast CT scan**.

- **Secondary Outcomes:**

  - **Postoperative complications** (Clavien-Dindo classification)

  - **Rehospitalization rate**

  - **Operative time** (minutes)

  - **Total laser energy used** (Joules)

Statistical Analysis Plan (SAP)

Sample Size Calculation

- **Power analysis was conducted using G*Power 3.1.9.7**.

- **95% confidence level (1-α = 0.95)** and **80% power (1-β = 0.80)** were used for the chi-square goodness-of-fit test.

- The minimum required sample size was **116 participants (58 per group)**.

- To compensate for data loss, the final sample size was **increased by 10% to 128 participants**.

Statistical Methods

All statistical analyses will be conducted using **IBM SPSS v25.0**. The following methods will be applied:

Primary Outcome Analysis: Stone-Free Rate

- **Chi-square test** to compare stone-free rates between groups.

- **Binary logistic regression analysis** to identify independent predictors of stone-free status.

Secondary Outcome Analysis

1. **Postoperative Complication Rate**

   o **Chi-square test** or **Fisher's exact test** for categorical data.

2. **Rehospitalization Rate**

   o **Chi-square test** for comparison between groups.

3. **Operative Time (minutes)**

   o **Independent samples t-test** (if normally distributed) or **Mann-Whitney U test** (if non-normally distributed).

4. **Total Laser Energy Used (Joules)**

   o **Independent samples t-test** or **Mann-Whitney U test** based on normality.

Normality Testing

- **Kolmogorov-Smirnov test** will assess the normality of continuous variables.

- Normally distributed variables will be presented as **mean ± standard deviation (SD)**.

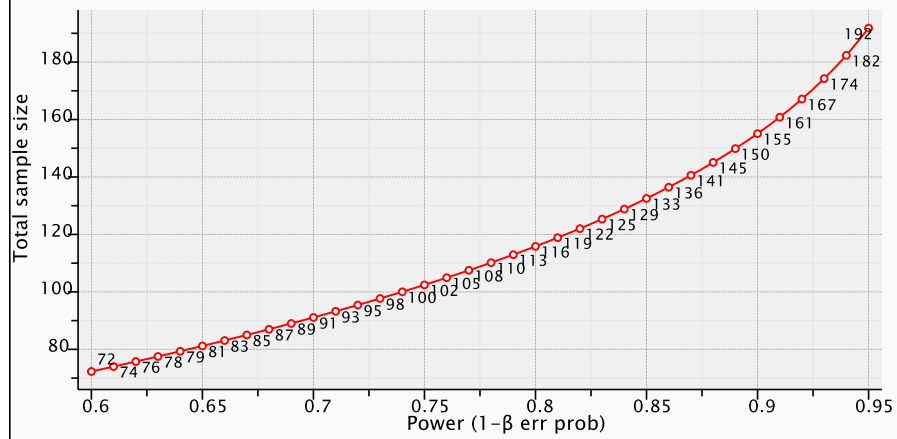- Non-normally distributed variables will be reported as **median (interquartile range, IQR)**.

Significance Level

- A **p-value <0.05** will be considered statistically significant.

Software

- All analyses will be performed using **IBM SPSS v25.0**.

χ² tests – Goodness-of-fit tests: Contingency tables
Df = 1, α err prob = 0.05, Effect size w = 0.26029

Ethical Board Approval Document in Turkish

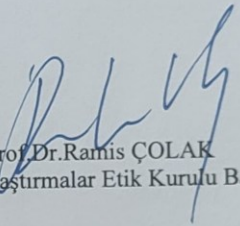Sayı: B.30.2.ODM.0.20.08/ 603-670   29.11.2024

Sayın Dr. Murat Gülşen

    Etik Kurulumuza sunmuş olduğunuz Retrograd intrarenal cerrahide pozisyon taşsızlığı etkiler mi?: Prospektif randomize kontrollü çalışma başlıklı OMÜ KAEK 2024/458 Karar nolu Klinik Çalışma   nitelikli araştırma projeniz amaç, gerekçe, yaklaşım ve yöntemle ilgili açıklamaları açısından Klinik Araştırmalar Etik Kurulu yönergesine göre incelenmiş ve etik açıdan bir sakınca olmadığına, çalışmanın süresi 6 ayı geçerse 6 aylık bildirimlerinin yapılmasına, çalışma tamamlandıktan sonra sonucunun tarafımıza en geç üç(3) ay içerisinde bildirilmesine 30.10.2024 tarihli Etik kurulumuzda oy birliği ile karar verilmiştir.

    Bilgilerinize arz/rica ederim.

Prof.Dr.Ramis ÇOLAK
Klinik Araştırmalar Etik Kurulu Başkanı