**STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN**

**Title:** Comparative Study Between eTEP-RS and IPOM Plus for Abdominal Wall Hernias

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**Version:** 1.0
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**NCT Number:** [To be assigned after registration]

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## 1. Background and Rationale

Abdominal wall hernias are common surgical conditions. Minimally invasive approaches like eTEP-RS (enhanced view totally extraperitoneal–retromuscular repair) and IPOM Plus (intraperitoneal onlay mesh with defect closure) are widely used. However, comparative data on clinical outcomes, complication rates, and recovery between these techniques are limited.

## 2. Objectives

**Primary Objective:**
To compare eTEP-RS and IPOM-PLUS in terms of:

- Operative time
- Recurrence rate
- Quality of life
- Post operative pain and chronic pain
- Surgical site infection
- Hospital stay
- Seroma and hematoma formation

**Secondary Objectives:**

- Calculation of conversion rate of eTEP-RS or IPOM PLUS to open hernia surgery.
- Intraoperative complications.

## 3. Study Design

- Type: Prospective, Randomized, Interventional Trial
- Model: Parallel Assignment
- Masking: None (Open Label)
- Allocation: Randomized
- Primary Purpose: Treatment

## 4. Eligibility Criteria

**Inclusion Criteria:**

- Adults aged 18–60 years
- Patient with uncomplicated ventral hernia with defect size 2- 5 cm
- Elective surgical cases(non- emergency)

**Exclusion Criteria:**

- Recurrent hernias
- Defect size > 5.0 cm
- Patient not giving consent
- Pregnant and lactating female
- Poor general condition
- Patient on anticoagulants
- Not fit for GA
- Patient with lateral hernias.
- Complicated hernias (e.g., strangulated, irreducible, obstructed)

## 5. Study Arms and Interventions

**Arm A:** eTEP-RS Technique
**Intervention:** Laparoscopic retromuscular mesh repair using the enhanced view totally extraperitoneal (eTEP-RS) technique.

**Arm B:** IPOM Plus Technique
**Intervention:** Intraperitoneal onlay mesh (IPOM Plus) repair involving laparoscopic fascial defect closure and mesh placement.

## 6. Outcome Measures

**Primary Outcome:**

- Pain score (VAS) at 24 hours post-op

**Secondary Outcomes:**

- Operative time (minutes)
- Duration of hospital stay (days)
- Time to return to normal activity (days)
- Postoperative complications (within 30 days)
- Recurrence (at 6 months follow-up)

## 7. Sample Size Calculation

Based on a previous pilot study, a sample of 87 patients per group (total n=174) achieves 80% power to detect a clinically significant difference in VAS score with a 5% level of significance.

## 8. Randomization Method

Simple randomization using odd- even method.

## 9. Data Collection and Management

Data will be recorded using standardized case record forms and entered into a secure password-protected database. Each participant will be assigned a unique ID to maintain confidentiality.

## 10. Ethical Considerations

The study has been approved by the Institutional Ethics Committee. Written informed consent will be obtained from all participants.

## 11. IPD Sharing Statement

De-identified individual participant data (IPD) and study documents will be made available upon reasonable request via email to the Principal Investigator.

## 12. References


1. Taşdelen HA. The extended-view totally extraperitoneal (eTEP) approach for incisional abdominal wall hernias: results from a single center. Surgical Endoscopy. 2022;*36*(6):4614-23.
2. Prakhar G, Parthasarathi R, Cumar B, Subbaiah R, Nalankilli VP, Praveen Raj P, et al. Extended View: Totally Extra Peritoneal (e-TEP) Approach for Ventral and Incisional Hernia-Early results from a single center. Surg Endosc. 2021;*35*(5):2005-13.
3. Buenafe AA, Lee-Ong A. Lateral release in the repair of large ventral hernia. Annals of Laparoscopic and Endoscopic Surgery. 2019;*4*.
4. Wiessner R, Vorwerk T, Tolla-Jensen C, Gehring A. Continuous Laparoscopic Closure of the Linea Alba with Barbed Sutures Combined with Laparoscopic Mesh Implantation (IPOM Plus Repair) As a New Technique for Treatment of Abdominal Hernias. Front Surg. 2017;*4*:62.
5. Jani K. Laparoscopic intra-peritoneal onlay mesh plus repair for ventral abdominal wall hernias-is there substance to the hype. Mini-invasive Surg. 2018;*2*(5):14.
6. Belyansky I, Daes J, Radu VG, Balasubramanian R, Reza Zahiri H, Weltz AS, et al. A novel approach using the enhanced-view totally extraperitoneal (eTEP) technique for laparoscopic retromuscular hernia repair. Surg Endosc. 2018;*32*(3):1525-32.


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# STATISTICAL ANALYSIS PLAN (SAP)

**Primary Outcome:**

- Comparison of VAS pain scores at 24 hours post-op between groups using **independent sample t-test** (if normally distributed) or **Mann–Whitney U test** (if non-parametric).

**Secondary Outcomes:**

- **Operative time, hospital stay, and return to activity:** analyzed with t-tests or non-parametric equivalents.
- **Complications and recurrence rates:** analyzed using **Chi-square test or Fisher's exact test**.
- **Confidence Intervals:** 95% CI will be reported for mean differences and proportions.
- **Significance level:** p-value < 0.05 will be considered statistically significant.

**Software:** Data will be analyzed using **SPSS version XX** or **R software**.

**Missing Data Handling:** Intention-to-treat principle will be applied. Sensitivity analyses may be conducted based on missing patterns.