Study Protocol

Official Title:
Comparison of Complication Rates of Onlay vs Sublay Mesh Repair of Incisional Hernia

Brief Title:
Complication Rate of Onlay vs Sublay Mesh Repair in Incisional Hernia

ClinicalTrials.gov Identifier:
NCT ID: Not Yet Assigned

Organization's Unique Protocol ID:
HMC-QAD-F No. IREB-1221

Study Type:
Interventional Study (Randomized Controlled Trial)

Study Design:
Parallel Assignment, Open Label

Sponsor:
Hayatabad Medical Complex, Peshawar, Pakistan

Responsible Party:
Principal Investigator

Principal Investigator:
Dr. Gohar Ali
Principal Investigator
Department of Surgery
Hayatabad Medical Complex, Peshawar, Pakistan

Ethics Approval:
Approved by Ethical Committee, Hayatabad Medical Complex, Peshawar
Approval Number: HMC-QAD-F No. IREB-1221

Study Start Date:
01 August 2020

Primary Completion Date:
31 August 2025

Study Completion Date:
15 September 2025

Study Design: Open-label, parallel group, randomized controlled trial

Objective:
To compare postoperative complication rates between **onlay** and **sublay** mesh repair in adult patients with incisional hernia.

Study Population:

- **Inclusion Criteria:**
    - Adults aged 18–60 years
    - Primary incisional hernia
    - Fit for open mesh repair
    - Able to provide informed consent
- **Exclusion Criteria:**
    - Obstructed/strangulated hernia
    - Recurrent hernia
    - BMI > 40
    - ASA ≥ 3 or severe comorbidities
    - Unable/unwilling to follow up

Sample Size: 350

Randomization:

- Randomized 1:1 to **onlay** or **sublay** repair
- Computer-generated random sequence

Interventions:

- **Experimental:** Sublay Mesh Repair — mesh placed in retromuscular/preperitoneal plane
- **Active Comparator:** Onlay Mesh Repair — mesh placed over anterior rectus sheath

Primary Outcome:

- Postoperative complication rate within 30 days (wound infection, seroma, hematoma, recurrence)

Secondary Outcomes:

- Hernia recurrence at 6 and 12 months
- Length of hospital stay
- Operative time

Follow-up:

- Clinical assessment on day 7, day 30, 6 months, and 12 months postoperatively

Ethics:

- Approved by Institutional Review Board, HMC (HMC-QAD-F No. IREB-1221)
- Written informed consent obtained from all participants

Data Management:

- Data recorded in secured database and standardized proforma
- Patient identifiers removed for any shared datasets.
- SPSS V23. Is used for data entry.