

Cover page

Study Protocol

Title:

**Comparison of Wound Infection in Patients Undergoing
Primary Closure and Open Technique in The Treatment of
Pilonidal Sinus**

Brief

Title:

Comparison of Primary closure vs Open wound Technique in Pilonidal Sinus Surgery

ClinicalTrials.gov Identifier

NCT Number: *Not yet assigned*

Unique Protocol ID

RMI_QAD_RCT_PILONOIDAL_sINUS

Study Type

Randomized Controlled Trial (RCT)

Study Sponsor / Conducting Institution

Hayatabad Medical Complex (HMC)
Peshawar, Pakistan

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: RMI_QAD_RCT_PILONOIDAL_sINUS

Study Type: Interventional, Randomized Controlled Trial

Recruitment & Study Duration:

Primary Purpose: Treatment

Interventional Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

- **Enrollment:** 76 participants (38 per arm)
- **Study Start Date**
January 01 2025 Actual
- **Primary Completion Date**
August 05 2026 Actual
- **Study Completion Date**
August 10 2026 Actual

Document date: May 05, 2025.

Study title:

Comparison of Wound Infection in Patients Undergoing Primary Closure and Open Technique in The Treatment of Pilonidal Sinus

Background and Rationale

Pilonidal sinus is a common condition of the sacrococcygeal area. Surgical excision remains the mainstay of treatment, but wound infection rates vary depending on closure technique. Previous studies suggest lower infection rates with primary closure compared to open technique. This trial aims to compare wound infection frequency between the two methods.

Objectives

- **Primary Objective:** Compare the frequency of wound infection within 30 days post-operation between primary closure and open technique.
- **Secondary Objectives:** Compare hospital stay duration, wound healing time, surgery time, and evaluate the effect of comorbidities (diabetes, hypertension, BMI, age, gender) on wound infection.

Methods

- **Design:** Parallel-arm randomized controlled trial.
- **Setting:** General Surgery Department, Rehman Medical Institute, Peshawar.
- **Duration:** January 2025 – August 2026.
- **Randomization:** Computer-generated sequence, 1:1 allocation.
- **Blinding:** Patients blinded; care providers and outcome assessors aware.
- **Sample Size:** 76 participants (38 per group).

Interventions

- **Arm A (Primary Closure):** Excision of sinus with closure using Prolene sutures and suction drain placement.
- **Arm B (Open Technique):** Excision of sinus with open wound packing using pyodine-soaked gauze, healing by secondary intention.

Eligibility

- **Inclusion:** Male and female, age 18–75, diagnosed pilonidal sinus.
- **Exclusion:** Debilitating disease, immunocompromised state (malignancy, tuberculosis).

Outcome Measures

- **Primary Outcome:** Wound infection (swelling, redness, pus/serous discharge) within 30 days post-operation.

- **Secondary Outcomes:** wound healing time, surgery time, stratified analysis of comorbidities.

Data Management:

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

References:

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2. Kober MM, Alapati U, Khachemoune A. Treatment options for pilonidal sinus. *Cutis.* 2018 Oct;102(4):E23–9. PubMed PMID: 30489572.
3. Jabbar MS, Bhutta MM, Puri N. Comparison between primary closure with Limberg Flap versus open procedure in treatment of pilonidal sinus, in terms of frequency of post-operative wound infection. *Pak J Med Sci.* 2018;34(1):49–53. doi:10.12669/pjms.341.13929 PubMed PMID: 29643877; PubMed Central PMCID: PMC5857027.
4. Maione F, D'Amore A, Milone M, Vertaldi S, Anoldo P, Chini A, et al. Endoscopic approach to complex or recurrent pilonidal sinus: A retrospective analysis. *Int Wound J.* 2023 Apr;20(4):1212–8. doi:10.1111/iwj.13980 PubMed PMID: 36271666; PubMed Central PMCID: PMC10031245.
5. Meinero P, La Torre M, Lisi G, Stazi A, Carbone A, Regusci L, et al. Endoscopic pilonidal sinus treatment (EPSiT) in recurrent pilonidal disease: a prospective international multicenter study. *Int J Colorectal Dis.* 2019 Apr;34(4):741–6. doi:10.1007/s00384-019-03256-8 PubMed PMID: 30719564.