Study Protocol

Official Title: A Prospective Randomized Controlled Trial Evaluating the Clinical Outcomes of Laser

NCT Number: NCT00000000

Document Date: July 15, 2025

This document is part of the ClinicalTrials.gov Results Submission.

Detailed Study Description

This is a prospective, randomized, open-label, parallel-group interventional clinical trial conducted at GSVM Medical College, Kanpur, aimed at comparing the clinical efficacy and safety of laser surgery using the FiLaC (Fistula Laser Closure) technique versus conventional open surgical procedures (fistulotomy or fistulectomy) in the management of fistula-in-ano.

A total of 100 adult patients (>18 years), with a confirmed diagnosis of intersphincteric or transsphincteric fistula-in-ano based on clinical evaluation and magnetic resonance (MR) fistulogram, were enrolled. Following informed consent and screening, patients were randomized in a 1:1 ratio into two arms:

Group A (Laser Surgery Group): Underwent minimally invasive FiLaC procedure using a 1470 nm diode laser and radial fiber probe for endofistular ablation.
Group B (Open Surgery Group): Underwent traditional open surgical procedures including fistulotomy, fistulectomy, or LIFT (Ligation of Intersphincteric Fistula Tract), depending on fistula anatomy.

All surgeries were performed under spinal anesthesia. Postoperative care was standardized across both groups. Patients were followed for a minimum of 3 months with structured clinical assessments at regular intervals.

Primary outcome measures included:
- Postoperative pain (VAS score within 7 days)
- Duration of hospital stay
- Time to resume normal daily activity
- Complete healing within 3 months (closure of both internal and external openings, cessation of discharge)

Secondary outcomes evaluated were:
- Recurrence rate at 3 months
- Wound infection requiring antibiotics
- Postoperative incontinence (flatus, solid or liquid stool)
- Requirement for reoperation
- Patient-reported satisfaction (scale of 1-10)

The study intends to assess whether the laser approach offers a meaningful improvement in postoperative morbidity, patient comfort, and quality of life, while also examining risk factors associated with poor surgical outcomes or recurrence.

Principal Investigator: Dr. Kamal Raj

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Statistical Analysis Plan

Official Title: A Prospective Randomized Controlled Trial Evaluating the Clinical Outcomes of Laser Surgery Versus Open Surgical Techniques in the Management of Fistula-in-Ano at a Tertiary Care Center

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This Statistical Analysis Plan supports the study results submitted to ClinicalTrials.gov.

STATISTICAL ANALYSIS PLAN (SAP)

Study Title:

A Prospective Randomized Controlled Trial Evaluating the Clinical Outcomes of Laser Surgery Versus Open Surgical Techniques in the Management of Fistula-in-Ano at a Tertiary Care Center

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Sponsor: GSVM Medical College, Kanpur

Principal Investigator: Dr. Kamal Raj

1. Objectives:

Primary Objective:

- To compare postoperative pain, hospital stay, time to return to activity, and complete healing at 3 months between laser and open surgery groups.

Secondary Objectives:

- To assess recurrence rate, postoperative complications, incontinence, reoperation requirement, and patient satisfaction.

2. Study Design:

- Prospective, randomized, parallel-group, open-label clinical trial
- Two arms (n=50 each): Laser Surgery (FiLaC) and Open Surgery (Fistulotomy/Fistulectomy)

3. Sample Size Justification:

- Assuming a moderate effect size (Cohen's d = 0.6), 80% power, and 5% alpha error, a total of 100 patients were enrolled (50 per arm), allowing for 10% dropout.

4. Statistical Methods:

- Descriptive statistics: Mean ± SD for continuous variables; frequency (%) for categorical variables
- Comparative analysis:
  * Independent t-test or Mann-Whitney U test for continuous variables
  * Chi-square test or Fisher's exact test for categorical variables

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

5. Handling of Missing Data:

- Missing outcome data will be handled using Last Observation Carried Forward (LOCF) where applicable

- Sensitivity analysis will be conducted to test the robustness of primary findings

6. Software:

- Analysis will be conducted using SPSS version 26.0 or equivalent statistical software

7. Interim Analysis:

- No interim analysis planned due to short duration and small sample size

8. Reporting:

- Results will be reported as per CONSORT guidelines with relevant tables, figures, and confidence intervals.

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