STUDY PROTOCOL

1. Title of the Study

Clinical Profile of Appendicitis and Comparative Study of Harmonic Scalpel (Seal and Cut) Versus Suture Ligation of the Base of Appendix During Laparoscopic Appendectomy

2. Protocol ID & Registration

Protocol ID: GSVM/GENSURG/APP/2025
ClinicalTrials.gov Identifier (NCT Number): [To be added]
Trial Registration Registry: ClinicalTrials.gov

3. Principal Investigator

Name: Dr. Apoorva Mathur
Designation: Principal Investigator
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4. Research Guide / Senior Author

Name: Dr. G.D Yadav
Designation: Professor & Head
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5. Background and Rationale

Acute appendicitis is a common surgical emergency. Laparoscopic appendectomy is widely accepted, with secure closure of the appendix base being a critical step. The harmonic scalpel offers an energy-based alternative to traditional suturing. This study aims to compare outcomes between these two techniques.

6. Study Objectives

Primary Objective:
- To compare operative time between harmonic scalpel and suture ligation techniques.

Secondary Objectives:
- To evaluate postoperative complications (leak, ileus, SSI)
- To assess hospital stay duration
- To document appendix position intraoperatively

7. Study Design

Study Type: Interventional (Clinical Trial)
Allocation: Randomized (computer-based)
Interventional Model: Parallel Assignment

Masking: Single (Participant)
Number of Arms: 2
Primary Purpose: Treatment

8. Participants

Sample Size: 60 patients (30 per group)

Inclusion Criteria:
- Age 15–60 years
- Diagnosed with uncomplicated acute appendicitis
- Consent to participate

Exclusion Criteria:
- Perforated/gangrenous appendix
- Pregnancy
- Coagulopathy or severe comorbid illness

9. Interventions

Arm A: Harmonic Scalpel Group (Experimental)
Laparoscopic appendectomy using harmonic scalpel to seal and divide appendix base.

Arm B: Suture Ligation Group (Active Comparator)
Laparoscopic appendectomy with intracorporeal suture ligation of appendix base.

10. Outcome Measures

Primary Outcome:
- Operative time (in minutes)

Secondary Outcomes:
- Position of appendix (intraoperative)
- Postoperative leak (within 7 days)
- Postoperative ileus (within 3 days)
- Surgical site infection (within 30 days)
- Hospital stay (in days)

11. Ethical Considerations

Approved by Institutional Ethics Committee, GSVM Medical College
Informed written consent will be obtained from all participants
Trial will be registered with ClinicalTrials.gov

12. Data Sharing Statement

De-identified individual data will be shared upon request for secondary analysis after 6 months of publication.

13. Timeline

Study Start: [April 2024]
Estimated Completion: [e.g., july 2025]

14. Funding and Support

No external funding. Supported by institutional resources.

Date- 01/05/2025