

# A study comparing laparoscopic and open surgery for treating appendicitis

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| <b>Submission date</b><br>26/12/2024   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>07/01/2025 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>07/01/2025       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Appendectomy is one of the most commonly performed surgeries, worldwide, to treat appendicitis, which requires surgical removal. There are two main techniques used for the procedure: open appendectomy and laparoscopic appendectomy. Both methods are widely practised, but there is no clear consensus on which is the best approach in terms of safety, effectiveness, and recovery outcomes. The study aims to recruit patients who are diagnosed with appendicitis and require surgery. Participants will be assigned to undergo either open or laparoscopic appendectomy. The goal is to compare the two techniques to determine which is safer, leads to faster recovery, has fewer complications, and improves patient satisfaction. Patients will be monitored throughout their recovery, with data collected on surgical outcomes, pain levels, infection rates, time to return to normal activities, and overall quality of life. Additional factors such as age, gender, and medical history will also be considered to see if specific groups benefit more from one technique over the other. The findings of this study aim to guide future surgical practices and improve the outcomes for patients undergoing appendectomy worldwide.

### Who can participate?

All patients aged between 12 to 70 years old presenting to the Ganesh Shankar Vidhyarthi Memorial Medical College hospital (India) with clinical and radiological evidence of appendicitis.

### What does the study involve?

Participants will be invited to join this study when they are diagnosed with appendicitis and require surgery. Eligibility criteria, including general health and consent, must be met before enrollment. Participants are assigned into one of two groups: one group will undergo open appendectomy, while the other will have laparoscopic appendectomy.

The study will monitor participants throughout their treatment and recovery. Participants will have their surgical outcomes, recovery time, and post-operative complications assessed. Additional tests, such as blood tests or imaging, may be conducted at the beginning and end of the study to evaluate recovery and overall health. Participants will also be asked about their experiences with the procedure, pain levels, and quality of life at regular intervals, after surgery. The study is expected to last one year, and results will help determine the most effective and safe approach to appendectomy for future patients.

What are the possible benefits and risks of participating?

**Benefits:**

There will be no immediate direct benefit to the participants in the study. The results of the study are likely to improve surgical practices in the future, benefiting patients with appendicitis by identifying the most effective and safest surgical technique.

**Risks:**

The risks involve the standard risks associated with the surgical procedures themselves, including infection, bleeding, and complications specific to the technique used (e.g., wound infection for open surgery or organ injury for laparoscopic surgery). There is a risk of additional stress or discomfort related to participating in a research study, such as longer hospital stays for follow-ups or extra tests.

**Safety Measures:**

Routine pre-operative and post-operative care will be provided to minimize risks. Patients will be closely monitored for complications during and after surgery, as per standard clinical guidelines. Participation will only proceed after informed consent, ensuring patients understand the potential risks and benefits.

Where is the study run from?

Ganesh Shankar Vidhyarthi Memorial Medical College, India

When is the study starting and how long is it expected to run for?

December 2022 to August 2024

Who is funding the study?

Ganesh Shankar Vidyarthi Memorial Medical College, India

Who is the main contact?

Dr Shriya Srivastava, gsvm\_knp@yahoo.co.in, shriyasri11.ss@gmail.com

## **Contact information**

**Type(s)**

Public, Scientific, Principal investigator

**Contact name**

Dr Shriya Srivastava

**ORCID ID**

<https://orcid.org/0009-0004-5197-8479>

**Contact details**

N.R.H. Hostel, Hallet (L.L.R.H.) hospital campus

G.S.V.M. Medical College

Kanpur

India

208002

+91 (0)6386552262

gsvm\_knp@yahoo.co.in

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

EC/210/Aug/2023

# Study information

## Scientific Title

Comparison of laparoscopic and open appendectomy in patients with acute appendicitis: a prospective study on postoperative outcomes

## Acronym

CLOAPP

## Study objectives

There is no significant difference between laparoscopic appendectomy and open appendectomy in terms of clinical outcomes (e.g., operative time, postoperative pain, complication rates, or recovery time) in the management of appendicitis.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 26/08/2023, Ethics committee, GSVM Medical College (Room no 125, 1st floor, GSVM Medical College, Kanpur, 208002, India; +91 (0)5122977822; ecgsvm@gmail.com), ref: EC/210 /Aug/2023

## Study design

Single-centre interventional non-randomized study, with purposive sampling for patient allocation

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Uncomplicated and complicated appendicitis

## Interventions

The study comparing two operative procedures - open and laparoscopic appendectomy aims to recruit 60 patients who are diagnosed with appendicitis and require surgery. Participants will be assigned to undergo either open or laparoscopic appendectomy, using non-randomised

purposive sampling. The aim is to compare the two techniques in terms of recovery, complications and patient satisfaction.

The patients will be followed every week for 2 months(60 days) post-surgery.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

1. Postoperative complications, including wound infection determined by redness, pain, and purulent discharge from the incision site; seroma defined as the localised collection of clear serous fluid without redness or pain, paralytic ileus defined as failure of return of bowel activity 24 hours after the surgery and intra-abdominal abscess defined as the localised collection of pus within the intra-peritoneal cavity on ultrasound, measured using event data collected from the Case Report Form at discharge.
2. Pain control measured using a Visual Analog Scale to compare the postoperative pain after the 1st postoperative day and at the time of discharge.
3. Length of hospital stay, defined as the number of nights spent in the hospital measured using patient medical records at discharge.

## **Key secondary outcome(s)**

1. Duration of surgery (in minutes), defined as the time of skin incision to the last skin suture for closure, measured using the patient records at the end of the surgery
2. Bowel sound was determined by auscultation via stethoscope, at 6, 12, 18 and 24 hours post-surgery
3. Return to routine activities (in days post-surgery), defined as resumption of routine household tasks, office activities and social life on the 15th post-operative day on OPD visit for follow-up
4. Satisfaction amongst patients measured using a questionnaire asking the patients to choose between three options: "extremely satisfied," "Satisfied," or "Unsatisfied" on the 15th post-operative day

## **Completion date**

31/08/2024

# **Eligibility**

## **Key inclusion criteria**

1. Clinical and radiological evidence of appendicitis
2. Aged between 12 and 70 years

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Mixed

## **Lower age limit**

12 years

**Upper age limit**

70 years

**Sex**

All

**Total final enrolment**

60

**Key exclusion criteria**

1. American Society of Anaesthesiologists (ASA) III or above
2. Hemodynamic instability
3. Chronic medical illness (like CAD, COPD)
4. Coagulation disorder

**Date of first enrolment**

02/09/2023

**Date of final enrolment**

29/08/2024

**Locations****Countries of recruitment**

India

**Study participating centre**

**G.S.V.M. Medical College**

Department of General Surgery

Kanpur

India

208002

**Sponsor information****Organisation**

Ganesh Shankar Vidyarthi Memorial Medical College

**ROR**

<https://ror.org/002ztb251>

**Funder(s)**

**Funder type**

University/education

**Funder Name**

Ganesh Shankar Vidyarthi Memorial Medical College

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |