

A study comparing laparoscopic and open surgery for treating appendicitis

Submission date 26/12/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/01/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/02/2026	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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 Vidhyarthi Memorial Medical College, India

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

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

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?
Results article		18/01/2025	02/02/2026	Yes	No