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A study comparing laparoscopic and open surgery for treating appendicitis

Submission date
26/12/2024

Recruitment status
No longer recruiting

Registration date
07/01/2025

Overall study status
Completed

Last Edited
07/01/2025

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Medical and other records, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
30/12/2022

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

Age group
Mixed

Lower age limit
12 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
60

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

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Sponsor type
University/education

Website
http://www.gsvmmedicalcollege.com/

ROR
https://ror.org/002ztb251

Funder(s)

Funder type
University/education

Funder Name
Ganesh Shankar Vidyarthi Memorial Medical College

Results and Publications

Publication and dissemination plan
Planned for publication in a peer reviewed journal

Intention to publish date
31/12/2024

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