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Using antibiotics during surgery to prevent infections after appendix removal

Submission date
09/05/2025

Recruitment status
No longer recruiting

Registration date
19/05/2025

Overall study status
Completed

Last Edited
13/08/2025

Condition category
Surgery

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

Plain English summary of protocol
Background and study aims
appendicitis is a common emergency condition treated with surgery, and a frequent complication is surgical site infection (SSI). This study aimed to find out whether washing the surgical wound with antibiotics during surgery would help to reduce SSI better than using regular normal saline.

Who can participate?
Patients aged 15 to 50 years who were diagnosed with acute appendicitis and underwent open surgery to remove the appendix at Abu Ghraib General Hospital in Baghdad were eligible to take part. People with certain health conditions like diabetes, heart problems, or decrease immunity were not included.

What does the study involve?
Participants were randomly assigned to two groups. One group had their wounds irrigated during surgery with antibiotic solutions (ceftriaxone and metronidazole), and the other group with saline only. All patients were followed up after surgery to check for signs of infection.

What are the possible benefits and risks of participating?
Participants received standard surgical care with an additional wound cleaning step. Risks were minimal and mainly related to common surgical complications. Antibiotic resistance or allergic reactions to antibiotics were avoided by excluding the risk individuals.

Where is the study run from?
The research was conducted at the General Surgery Department, Abu Ghraib General Hospital, Baghdad, Iraq.

When is the study starting and how long is it expected to run for?
May 2023 to April 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr. Mahmood Hasen Shuhata, Dp.dentistryb@huc.edu.iq

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
Ethical Committee Approval No.: 7 – Al-Hadi University, July 2023

Study information

Scientific Title
Role of intraoperative antibiotics wound irrigation in reducing surgical site infection following open appendectomy: a randomized controlled trial

Acronym
AIWI-Appendix

Study objectives
Intraoperative wound irrigation with a combination of ceftriaxone and metronidazole significantly reduces the incidence of surgical site infections (SSIs) after open appendectomy compared to irrigation with normal saline alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/06/2023, Ethics Committee of Al-Hadi University (60th street, Al-Douro, Baghdad, 10011, Iraq; 6484; huc.edu@huc.edu.iq), ref: 891

Study design
Interventional double blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Prevention of surgical site infection in patients who had undergone open appendectomies

Interventions
The two study arms were:
A- Experimental Group (Antibiotic Irrigation Group):
Patients in this group underwent open appendectomy with intraoperative wound irrigation performed layer by layer using a ceftriaxone solution (200 mg/20 mL) diluted in normal saline, followed by a metronidazole solution (50 mg/10 mL). The irrigation was applying to both deep (after closure of the internal oblique muscle) and superficial (after closure of the external oblique muscle) layers before wound closure.

B- Control Group (Saline Irrigation Group:
Patients in this group underwent the same surgical procedures but received layer by layer wound irrigation with 0.9% normal saline only, with no antibiotic usage.
All patients had received standard preoperative IV antibiotic (ceftriaxone 1 g and metronidazole 500 mg) within 24 hours before the surgery in line with hospital guidelines.

The total duration of the treatment was limited to the surgical procedure (single administration only), and the postoperative follow up for all study arms lasted for 30 days with assessments on postoperative days 10, 15, and 30.

Randomization was conducted using simple randomization through the online tool www.random.org. This website generated numbers into two groups so we used these numbers to allocate patients into the study groups (for example: if number 5 was allocated in the experimental group, the fifth patient in the study was assigned in the experimental group). The trial was double blind: patients and outcome assessors were blinded to the group allocation, although operating surgeons were aware due to the nature of the intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure
Surgical site infection defined and assessed using CDC criteria at postoperative days 10, 15, and 30.

Secondary outcome measures
1. Preoperative C-reactive protein and white blood cell counts measured using blood test
2. Postoperative SSI risk measured using the Centers for Disease Control and Prevention (CDC) criteria. Patients were evaluated through clinical examination during postoperative follow up on days 10, 15, and 30 after discharge.
3. SSI incidence measured using patient records up to 30 days post operatively
4. Length of hospital stay (days) from day of surgery to discharge and re-admissions measured using patient records

Overall study start date
01/05/2023

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. Aged 15 to 50 years
2. Diagnosed with acute appendicitis
3. Undergoing open appendectomy
4. Provided informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
15 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
388

Total final enrolment

410

Key exclusion criteria
1. Diabetes mellitus, heart disease, immunocompromised state
2. ASA Grade III or higher
3. Steroid use
4. Allergy to penicillin or cephalosporins

Date of first enrolment
01/07/2023

Date of final enrolment
03/12/2024

Locations

Countries of recruitment
Iraq

Study participating centre
Abu Ghraib General Hospital
Abu Ghraib district, Al-Karkh
Baghdad
Iraq
10081

Sponsor information

Organisation
Al-Hadi University College

Sponsor details
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Sponsor type
University/education

Website
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ROR
https://ror.org/03nj9d526

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Manuscript submitted to BMC Surgery (under review)

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request from the corresponding author :
Mr. Mahmood Hasen Shuhata
Email: Dp.dentistryb@huc.edu.iq

Type of data to be shared:
Non identified individual participants' data including age, gender, CRP and WBC levels, presence of perforated appendix, group allocation (antibiotic or saline), and incidence of surgical site infection.

When data will be available:
Immediately upon publication of the results or earlier upon request and approval.

How long data will be available:
For a minimum of 5 years following publication.

Access criteria:
data will be shared with qualified researchers for academic purposes. Requests must include a brief description of the proposed research and will be reviewed by the study team to ensure appropriate use.

Mechanism:
Data will be shared electronically via secure email or file sharing platforms

Consent and anonymisation:
All data will be fully anonymised before sharing. Informed consent for participation was obtained from all study participants, including consent for data use in research

Restrictions:
No legal restrictions apply. Data sharing will comply with ethical standards and protect participant confidentiality.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Arabic		19/05/2025	No	Yes
Participant information sheet	in English		19/05/2025	No	Yes
Results article		12/08/2025	13/08/2025	Yes	No