ISRCTN15780064 https://doi.org/10.1186/ISRCTN15780064

Comparative study of three different antibiotic combinations used for the management of acute appendicitis

Submission date
27/10/2020

Recruitment status
No longer recruiting

Registration date
29/10/2020

Overall study status
Completed

Last Edited
20/04/2026

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Appendicitis is inflammation of the appendix (a small pouch connected to the large intestine). It is treated with surgery to remove the appendix. The aims of this study are to identify the microorganisms that cause acute appendicitis, compare the effectiveness and safety of managing acute appendicitis with three different antibiotics that are already used in clinical practice, and study their effect on the microorganisms. The researchers would also like to diagnose acute kidney injury with new biomarkers in urine and blood earlier.

Who can participate?
Participants aged 18 or older with acute appendicitis who are undergoing surgery

What does the study involve?
The study does not change the course of treatment. The researchers will take blood and urine samples and rectal swabs before and after discharge from the hospital.

What are the possible benefits and risks of participating?
During the study patients will not be at a greater health risk. On the contrary, the function of their organs and the level of antibiotics in their blood will be carefully monitored.

Where is the study run from?
University Medical Centre Ljubljana (Slovenia)

When is the study starting and how long is it expected to run for?
August 2020 to April 2024

Who is funding the study?
University Medical Centre Ljubljana (Slovenia)

Who is the main contact?
Nika Obolnar, nika.obolnar@ir-rs.si

Contact information

Type(s)
Scientific

Contact name
Mrs Nika Obolnar

Contact details
Vrhpolje 60
Kamnik
Slovenia
1240
+386 (0)51205622
nika.obolnar@ir-rs.si

Additional identifiers

Protocol serial number
0120-583/2019/7

Study information

Scientific Title
Prospective randomized comparative study of efficiency and safety of gentamicin with metronidazole, cefuroxime with metronidazole, and ertapenem in the management of community-acquired acute appendicitis in patients who are also treated by surgical management of intra-abdominal infections

Study objectives
There is no difference between the efficacy and safety of usage of gentamicin+metronidazole, cefuroxime+metronidazole or ertapenem. In a group treated with aminoglycosides, the antimicrobial susceptibility of E. coli isolated from rectal swab before and after treatment is the same, which is the same as other antibiotic regimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2020, National Medical Ethics Committee of Slovenia (Ministry of Health, Štefanova 5, SI-1000 Ljubljana, Slovenia; +386 (0)1 478 60 01, +386 (0)1 478 69 13; kme.mz@gov.si), ref: 0120-583/2019/7

Primary study design
Interventional

Study design
Prospective randomized comparative study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute appendicitis

Interventions
Patients will be treated with surgery as usual, and one of three (combinations of) antibiotics: gentamicin+metronidazole, cefuroxime+metronidazole and ertapenem.

After signing an agreement to participate in the study, the researchers will take blood and urine samples and also a rectal swab for identifying E. coli spp. in the rectum. Patients will undergo standard procedures, including transfer to the Department for Abdominal Surgery, where they will receive the first dose of one of three already registered and used antibiotics, and then undergo an appendectomy. During the hospital stay the researchers will take another two blood and urine samples, the last one on the day of discharge from the hospital, when another rectal swab will be taken. The duration of antibiotic therapy is predicted to be short, lasting 4 days depending also on clinical grading of appendicitis and guidelines. After 30 days the researchers will check whether the patient has any complications, including a medical or surgical re-intervention.

Urine and blood samples will be examined at the Institute of Clinical Chemistry and Biochemistry. A smaller amount will be stored on ice for further examinations of biomarkers of acute kidney injury.

During an appendectomy according to the protocol a part of an appendix is examined by a pathologist for the exclusion of appendiceal malignancy. In this study the tissue will be held at the Institute of Pathology, where the diagnosis will be done. Then a part of the appendix will be further examined by a microbiologist at the Institute of Microbiology and Immunology or Comparative laboratory in the EU, based on scientific collaboration to laboratories. They will study the microbiome of the infected appendix, the patients' DNA material will be destroyed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gentamicin + metronidazole, cefuroxime + metronidazole, ertapenem

Primary outcome(s)
1. Differential blood count (DBC), C-reactive protein (CRP), albumins and markers of renal function (blood urea, creatinine and glomerular filtration rate (GFR)) measured using blood samples taken at baseline, on the second day after surgery and the day of discharge from the hospital
2. Urine specific gravity, pH, proteins, glucose, bilirubin, urobilinogen, white and red blood cells, methylketones, haemoglobin in urine and sediment in urine (white and red blood cells, bacteria and epithelial cells) measured using urine samples taken at baseline, on the second day after surgery and the day of discharge from the hospital
3. E. coli spp. in the rectum measured using rectal swab at baseline and day of discharge

4. Pathological diagnostics using microscopy and sterile instruments as soon as the appendix is safely removed. If the surgery is going to be in the night, then the material will be transferred in the morning.
5. Microbiome studied using 16S rDNA sequencing after the appendix is safely removed and the pathologist has performed the diagnostics

Key secondary outcome(s)
Complications of appendectomy measured clinically after 30 days

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Examined in the ER abdominal surgery department of UCML
2. Adults aged ≥18 years
3. Healthy individuals, no other illnesses
4. Diagnosed with acute appendicitis
5. Indicated for surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
166

Key exclusion criteria
1. Minors aged <18 years
2. Polymorbid individual
3. Patient with a serious illness
4. Pregnant or breastfeeding women
5. Known renal impairment

Date of first enrolment

09/11/2020

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Slovenia

Study participating centre
University Medical Centre Ljubljana
Zaloška cesta 2
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Ljubljana University Medical Centre

ROR
https://ror.org/01nr6fy72

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ljubljana University Medical Centre

Funder Name
Univerza v Ljubljani

Alternative Name(s)
University of Ljubljana, University of Ljubljana Slovenia, University of Ljubljana in Slovenia, Universitas Labacensis, UL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Slovenia

Results and Publications

Individual participant data (IPD) sharing plan
The data will be published in an article and a PhD thesis, otherwise it will not be made public.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/04/2026	20/04/2026	Yes	No