

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

Submission date 27/10/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/09/2023	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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

Study design

Prospective randomized comparative study

Primary study design

Interventional

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

Adult

Lower age limit

18 years

Sex

All

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