

Association of the type of antibiotics used at the time of appendix removal in children with appendicitis with wound infections after the surgery

Submission date 09/02/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/02/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/09/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

The aim of this study is to find out whether the type of antibiotics given at the time children are undergoing removal of their appendix for uncomplicated appendicitis is better than the next most commonly used alternative in terms of children experiencing wound infections in the 4 weeks after surgery.

Who can participate?

Children up to the age of 16 years who have had their appendix removed for uncomplicated appendicitis during the time period from 01/01/2014 to 31/12/2018 and whose data were collected during routine surveillance carried out in Switzerland

What does the study involve?

The study only analyses data available through mandatory routine surveillance in Switzerland.

What are the possible benefits and risks of participating?

The study does not pose a risk nor present a benefit for children whose data are analysed.

Where is the study run from?

University of Basel Children's Hospital (Switzerland)

When is the study starting and how long is it expected to run for?

December 2018 to December 2019

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Julia Bielicki, jbielick@sgul.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Julia Bielicki

Contact details

Spitalstrasse 33

Basel

Switzerland

4056

+41 (0)617041212

julia.bielicki@ukbb.ch

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Swiss SSI Surveillance

Study information

Scientific Title

Association between perioperative prophylaxis with cefuroxime plus metronidazole or amoxicillin/clavulanic acid and surgical site infections in pediatric appendectomy: a Swiss retrospective cohort study

Study objectives

Evidence supporting the use of specific antibiotic regimes in perioperative antibiotic prophylaxis administered in children undergoing appendectomy for uncomplicated appendicitis is limited. It is hypothesised that a cephalosporin-based regimen may be more effective than a non-cephalosporin-based regimen.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/01/2019, the local ethics committee (Ethikkommission Zentral- und Nordwestschweiz [EKNZ], Ethikkommission Nordwest- und Zentralschweiz (EKNZ), Hebelstrasse 53, 4056 Basel, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: 2018-02252

Study design

Retrospective cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Children undergoing appendectomy for uncomplicated appendicitis

Interventions

The study only analyses data available through mandatory routine surveillance in Switzerland. All children up to the age of 16 years who have had their appendix removed for uncomplicated appendicitis during the time period from 01/01/2014 to 31/12/2018 and whose data were collected during routine surveillance carried out in Switzerland are included. The interventions of interest for the comparative effectiveness analysis are the application of perioperative antibiotic prophylaxis with amoxicillin/clavulanate or cefuroxime plus metronidazole as recorded in mandatory national surgical site infection surveillance in Switzerland.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Amoxicillin/clavulanate (intravenous application), cefuroxime plus metronidazole (intravenous application)

Primary outcome(s)

Surgical site infections (SSIs) up to 30 days after appendectomy as captured within the Swiss national SSI surveillance programme

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/12/2019

Eligibility

Key inclusion criteria

Patients up to 16 years of age undergoing appendectomy for uncomplicated appendicitis in the study period from 2014 to 2018 in Switzerland

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 years

Sex

All

Total final enrolment

3839

Key exclusion criteria

1. Older than 16 years of age
2. Appendectomy carried out for complicated appendicitis (perforated, established abscess)
3. Receipt of antibiotics for perioperative prophylaxis other than the two target regimens
4. No perioperative antibiotic prophylaxis applied
5. Patients with missing procedure-related data

Date of first enrolment

01/01/2014

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

Switzerland

Study participating centre

University of Basel Children's Hospital

Spitalstrasse 33

Basel

Switzerland

4056

Sponsor information

Organisation

University of Basel Children's Hospital

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Dr Julia Bielicki (julia.bielicki@ukbb.ch).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/09/2023	26/09/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes