

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

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<b>Registration date</b> 23/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/09/2023	<b>Condition category</b> 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](mailto: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?
<a href="#">Results article</a>		25/09/2023	26/09/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes